

106TH CONGRESS  
1ST SESSION

# S. 374

To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 to protect consumers in managed care plans and other health coverage.

---

## IN THE SENATE OF THE UNITED STATES

FEBRUARY 4, 1999

Mr. CHAFEE (for himself, Mr. GRAHAM, Mr. LIEBERMAN, Mr. SPECTER, Mr. BAUCUS, Mr. ROBB and Mr. BAYH) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

---

## A BILL

To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 to protect consumers in managed care plans and other health coverage.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

### 3   **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4       (a) **SHORT TITLE.**—This Act may be cited as the  
5       “Promoting Responsible Managed Care Act of 1999”.

6       (b) **TABLE OF CONTENTS.**—The table of contents of  
7       this Act is as follows:

- Sec. 1. Short title; table of contents.
- Sec. 2. Definitions.
- Sec. 3. Preemption; State flexibility; construction.
- Sec. 4. Regulations.

## TITLE I—PROMOTING RESPONSIBLE MANAGED CARE

### Subtitle A—Grievance and Appeals

- Sec. 101. Definitions and general provisions relating to grievance and appeals.
- Sec. 102. Utilization review activities.
- Sec. 103. Establishment of process for grievances.
- Sec. 104. Coverage determinations.
- Sec. 105. Internal appeals (reconsiderations).
- Sec. 106. External appeals (reviews).

### Subtitle B—Consumer Information

- Sec. 111. Health plan information.
- Sec. 112. Health care quality information.
- Sec. 113. Confidentiality and accuracy of enrollee records.
- Sec. 114. Quality assurance.

### Subtitle C—Patient Protection Standards

- Sec. 121. Emergency services.
- Sec. 122. Enrollee choice of health professionals and providers.
- Sec. 123. Access to approved services.
- Sec. 124. Nondiscrimination in delivery of services.
- Sec. 125. Prohibition of interference with certain medical communications.
- Sec. 126. Provider incentive plans.
- Sec. 127. Provider participation.
- Sec. 128. Required coverage for appropriate hospital stay for mastectomies and lymph node dissections for the treatment of breast cancer.
- Sec. 129. Promoting good medical practice.

### Subtitle D—Enhanced Enforcement Authority

- Sec. 141. Investigations and reporting authority, injunctive relief authority, and increased civil money penalty authority for Secretary of Health and Human Services for violations of patient protection standards.
- Sec. 142. Authority for Secretary of Labor to impose civil penalties for violations of patient protection standards.

## TITLE II—PATIENT PROTECTION STANDARDS UNDER THE PUBLIC HEALTH SERVICE ACT

- Sec. 201. Application to group health plans and group health insurance coverage.
- Sec. 202. Application to individual health insurance coverage.

## TITLE III—PATIENT PROTECTION STANDARDS UNDER THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974

- Sec. 301. Application of patient protection standards to group health plans and group health insurance coverage under the Employee Retirement Income Security Act of 1974.

Sec. 302. Enforcement for economic loss caused by coverage determinations.

TITLE IV—PATIENT PROTECTION STANDARDS UNDER THE  
INTERNAL REVENUE CODE OF 1986

Sec. 401. Amendments to the Internal Revenue Code of 1986.

TITLE V—EFFECTIVE DATES; COORDINATION IN  
IMPLEMENTATION

Sec. 501. Effective dates.

Sec. 502. Coordination in implementation.

**1 SEC. 2. DEFINITIONS.**

**2 (a) INCORPORATION OF GENERAL DEFINITIONS.—**

**3** The provisions of section 2971 of the Public Health Serv-  
**4** ice Act shall apply for purposes of this section, section  
**5** 3, and title I in the same manner as they apply for pur-  
**6** poses of title XXVII of such Act.

**7 (b) SECRETARY.—**Except as otherwise provided, for  
**8** purposes of this section and title I, the term “Secretary”  
**9** means the Secretary of Health and Human Services, in  
**10** consultation with the Secretary of Labor and the Sec-  
**11** retary of the Treasury, and the term “appropriate Sec-  
**12** retary” means the Secretary of Health and Human Serv-  
**13** ices in relation to carrying out title I under sections 2707  
**14** and 2751 of the Public Health Service Act, the Secretary  
**15** of Labor in relation to carrying out title I under section  
**16** 714 of the Employee Retirement Income Security Act of  
**17** 1974, and the Secretary of the Treasury in relation to car-  
**18** rying out title I under chapter 100 and section 4980D  
**19** of the Internal Revenue Code of 1986.

1 (c) ADDITIONAL DEFINITIONS.—For purposes of this  
 2 section and title I:

3 (1) APPLICABLE AUTHORITY.—The term “ap-  
 4 plicable authority” means—

5 (A) in the case of a group health plan, the  
 6 Secretary of Health and Human Services and  
 7 the Secretary of Labor; and

8 (B) in the case of a health insurance issuer  
 9 with respect to a specific provision of title I, the  
 10 applicable State authority (as defined in section  
 11 2791(d) of the Public Health Service Act), or  
 12 the Secretary of Health and Human Services, if  
 13 such Secretary is enforcing such specific provi-  
 14 sion under section 2722(a)(2) or 2761(a)(2) of  
 15 the Public Health Service Act.

16 (2) CLINICAL PEER.—The term “clinical peer”  
 17 means, with respect to a review or appeal, a physi-  
 18 cian (allopathic or osteopathic) or other health care  
 19 professional who holds a non-restricted license in a  
 20 State and who is appropriately credentialed, li-  
 21 censed, certified, or accredited in the same or similar  
 22 specialty as manages (or typically manages) the  
 23 medical condition, procedure, or treatment under re-  
 24 view or appeal and includes a pediatric specialist  
 25 where appropriate; except that only a physician may

1 be a clinical peer with respect to the review or ap-  
 2 peal of treatment rendered by a physician.

3 (3) HEALTH CARE PROVIDER.—The term  
 4 “health care provider” includes a physician or other  
 5 health care professional, as well as an institutional  
 6 provider of health care services.

7 (4) NONPARTICIPATING.—The term “non-  
 8 participating” means, with respect to a health care  
 9 provider that provides health care items and services  
 10 to a participant, beneficiary, or enrollee under a  
 11 group health plan or health insurance coverage, a  
 12 health care provider that is not a participating  
 13 health care provider with respect to such items and  
 14 services.

15 (5) PARTICIPATING.—The term “participating”  
 16 means, with respect to a health care provider that  
 17 provides health care items and services to a partici-  
 18 pant, beneficiary, or enrollee under a group health  
 19 plan or health insurance coverage offered by a  
 20 health insurance issuer, a health care provider that  
 21 furnishes such items and services under a contract  
 22 or other arrangement with the plan or issuer.

23 **SEC. 3. PREEMPTION; STATE FLEXIBILITY; CONSTRUCTION.**

24 (a) CONTINUED APPLICABILITY OF STATE LAW  
 25 WITH RESPECT TO HEALTH INSURANCE ISSUERS.—

1           (1) IN GENERAL.—Subject to paragraphs (2)  
 2           and (3), title I shall not be construed to supersede  
 3           any provision of State law which establishes, imple-  
 4           ments, or continues in effect any standard or re-  
 5           quirement solely relating to health insurance issuers  
 6           in connection with group health insurance coverage  
 7           except to the extent that such standard or require-  
 8           ment prevents the application of a requirement of  
 9           such title.

10           (2) CONTINUED PREEMPTION WITH RESPECT  
 11           TO GROUP HEALTH PLANS.—Nothing in title I shall  
 12           be construed to affect or modify the provisions of  
 13           section 514 of the Employee Retirement Income Se-  
 14           curity Act of 1974 with respect to group health  
 15           plans.

16           (3) CONSTRUCTION WITH RESPECT TO TIME  
 17           PERIODS.—Subject to paragraph (2), nothing in title  
 18           I shall be construed to prohibit a State from estab-  
 19           lishing, implementing, or continuing in effect any re-  
 20           quirement or standard that uses a shorter period of  
 21           time, than that provided under such title, for any in-  
 22           ternal or external appeals process to be used by  
 23           health insurance issuers.

24           (b) RULES OF CONSTRUCTION.—Nothing in title I  
 25           (other than section 128) shall be construed as requiring

1 a group health plan or health insurance coverage to pro-  
 2 vide specific benefits under the terms of such plan or cov-  
 3 erage.

4 (c) DEFINITIONS.—For purposes of this section:

5 (1) STATE LAW.—The term “State law” in-  
 6 cludes all laws, decisions, rules, regulations, or other  
 7 State action having the effect of law, of any State.  
 8 A law of the United States applicable only to the  
 9 District of Columbia shall be treated as a State law  
 10 rather than a law of the United States.

11 (2) INCLUSION OF POLITICAL SUBDIVISIONS OF  
 12 A STATE.—The term “State” also includes any polit-  
 13 ical subdivisions of a State or any agency or instru-  
 14 mentality thereof.

15 (d) TREATMENT OF RELIGIOUS NONMEDICAL PRO-  
 16 VIDERS.—

17 (1) IN GENERAL.—Nothing in this Act (or the  
 18 amendments made thereby) shall be construed to—

19 (A) restrict or limit the right of group  
 20 health plans, and of health insurance issuers of-  
 21 fering health insurance coverage in connection  
 22 with group health plans, to include as providers  
 23 religious nonmedical providers;

24 (B) require such plans or issuers to—

1 (i) utilize medically based eligibility  
 2 standards or criteria in deciding provider  
 3 status of religious nonmedical providers;

4 (ii) use medical professionals or cri-  
 5 teria to decide patient access to religious  
 6 nonmedical providers;

7 (iii) utilize medical professionals or  
 8 criteria in making decisions in internal or  
 9 external appeals from decisions denying or  
 10 limiting coverage for care by religious non-  
 11 medical providers; or

12 (iv) compel a participant or bene-  
 13 ficiary to undergo a medical examination  
 14 or test as a condition of receiving health  
 15 insurance coverage for treatment by a reli-  
 16 gious nonmedical provider; or

17 (C) require such plans or issuers to ex-  
 18 clude religious nonmedical providers because  
 19 they do not provide medical or other data other-  
 20 wise required, if such data is inconsistent with  
 21 the religious nonmedical treatment or nursing  
 22 care provided by the provider.

23 (2) RELIGIOUS NONMEDICAL PROVIDER.—For  
 24 purposes of this subsection, the term “religious non-  
 25 medical provider” means a provider who provides no

1 medical care but who provides only religious non-  
 2 medical treatment or religious nonmedical nursing  
 3 care.

4 **SEC. 4. REGULATIONS.**

5 The Secretaries of Health and Human Services,  
 6 Labor, and the Treasury shall issue such regulations as  
 7 may be necessary or appropriate to carry out this Act.  
 8 Such regulations shall be issued consistent with section  
 9 104 of Health Insurance Portability and Accountability  
 10 Act of 1996. Such Secretaries may promulgate any in-  
 11 terim final rules as the Secretaries determine are appro-  
 12 priate to carry out this Act.

13 **TITLE I—PROMOTING**  
 14 **RESPONSIBLE MANAGED CARE**  
 15 **Subtitle A—Grievance and Appeals**

16 **SEC. 101. DEFINITIONS AND GENERAL PROVISIONS RELAT-**  
 17 **ING TO GRIEVANCE AND APPEALS.**

18 (a) DEFINITIONS.—In this subtitle:

19 (1) AUTHORIZED REPRESENTATIVE.—The term  
 20 “authorized representative” means, with respect to a  
 21 covered individual, an individual who—

22 (A) is—

23 (i) any treating health care profes-  
 24 sional of the covered individual (acting  
 25 within the scope of the professional’s li-

1                   cense or certification under applicable  
2                   State law), or

3                   (ii) any legal representative of the  
4                   covered individual (or, in the case of a de-  
5                   ceased individual, the legal representative  
6                   of the estate of the individual),

7                   regardless of whether such professional or rep-  
8                   resentative is affiliated with the plan or issuer  
9                   involved; and

10                  (B) is acting on behalf of the covered indi-  
11                  vidual with the individual's consent.

12                  (2) COVERAGE DETERMINATION.—The term  
13                  “coverage determination” means any of the follow-  
14                  ing:

15                  (A) A decision by a group health plan or  
16                  health insurance issuer as to whether to provide  
17                  benefits or payment for such benefits, including  
18                  such a decision resulting from the application of  
19                  utilization review (as defined in section  
20                  102(a)(3)) or relating to benefits required  
21                  under section 121 or 128.

22                  (B) A decision of a group health plan or  
23                  health insurance issuer (or the failure of such  
24                  a plan or issuer) with respect to meeting a re-

1           requirement described in section 122(a), 122(b),  
2           122(c), 122(d), 123, or 124.

3           (C) Pursuant to section 104(d)(2), the fail-  
4           ure of a group health plan or health insurance  
5           issuer to provide timely notice under section  
6           104(d).

7           (3) COVERED INDIVIDUAL.—The term “covered  
8           individual” means an individual who is a participant  
9           or beneficiary in a group health plan or an enrollee  
10          in health insurance coverage offered by a health in-  
11          surance issuer.

12          (4) GRIEVANCE.—The term “grievance” means  
13          any complaint or dispute other than one involving a  
14          coverage determination.

15          (5) RECONSIDERATION.—The term “reconsider-  
16          ation” is defined in section 105(a)(7).

17          (6) UTILIZATION REVIEW.—The term “utiliza-  
18          tion review” is defined in section 102(a)(3).

19          (b) SUMMARY OF RIGHTS OF INDIVIDUALS.—In ac-  
20          cordance with the provisions of this subtitle, a covered in-  
21          dividual has the following rights with respect to a group  
22          health plan and with respect to a health insurance issuer  
23          in connection with the provision of health insurance cov-  
24          erage:

1           (1) The right to have grievances between the  
2 covered individual and the plan or issuer heard and  
3 resolved as provided in section 103.

4           (2) The right to a timely coverage determina-  
5 tion as provided in section 104.

6           (3) The right to request expedited treatment of  
7 a coverage determination as provided in section  
8 104(c).

9           (4) If dissatisfied with any part of a coverage  
10 determination, the following appeal rights:

11           (A) The right to a timely reconsideration  
12 of an adverse coverage determination as pro-  
13 vided in section 105.

14           (B) The right to request expedited treat-  
15 ment of such a reconsideration as provided in  
16 section 105(c).

17           (C) If, as a result of a reconsideration of  
18 the adverse coverage determination, the plan or  
19 issuer affirms, in whole or in part, its adverse  
20 coverage determination, the right to request  
21 and receive a review of, and decision on, such  
22 determination by a qualified external appeal en-  
23 tity as provided in section 106.

24           (c) REQUIREMENTS.—

1           (1) PROCEDURES.—A group health plan, and a  
 2           health insurance issuer in connection with the provi-  
 3           sion of health insurance coverage shall, with respect  
 4           to the provision of benefits under such plan or  
 5           coverage—

6                   (A) establish and maintain—

7                           (i) grievance procedures in accordance  
 8                           with section 103;

9                           (ii) procedures for coverage deter-  
 10                           minations consistent with section 104; and

11                           (iii) appeals procedures for adverse  
 12                           coverage determinations in accordance with  
 13                           sections 105 and 106; and

14                   (B) provide for utilization review consistent  
 15                   with section 102.

16           (2) DELEGATION.—A group health plan or a  
 17           health insurance issuer in connection with the provi-  
 18           sion of health insurance coverage that delegates any  
 19           of its responsibilities under this subtitle to another  
 20           entity or individual through which the plan or issuer  
 21           provides health care services shall ultimately be re-  
 22           sponsible for ensuring that such entity or individual  
 23           satisfies the relevant requirements of this subtitle.

24 **SEC. 102. UTILIZATION REVIEW ACTIVITIES.**

25           (a) COMPLIANCE WITH REQUIREMENTS.—

1           (1) IN GENERAL.—A group health plan, and a  
2           health insurance issuer in connection with the provi-  
3           sion of health insurance coverage, shall conduct utili-  
4           zation review activities in connection with the provi-  
5           sion of benefits under such plan or coverage only in  
6           accordance with a utilization review program that  
7           meets the requirements of this section.

8           (2) USE OF OUTSIDE AGENTS.—Nothing in this  
9           section shall be construed as preventing a group  
10          health plan or health insurance issuer from arrang-  
11          ing through a contract or otherwise for persons or  
12          entities to conduct utilization review activities on be-  
13          half of the plan or issuer, so long as such activities  
14          are conducted in accordance with a utilization review  
15          program that meets the requirements of this section.

16          (3) UTILIZATION REVIEW DEFINED.—For pur-  
17          poses of this section, the terms “utilization review”  
18          and “utilization review activities” mean procedures  
19          used to monitor or evaluate the clinical necessity,  
20          appropriateness, efficacy, or efficiency of health care  
21          services, procedures or settings, and includes pro-  
22          spective review, concurrent review, second opinions,  
23          case management, discharge planning, or retrospec-  
24          tive review.

25          (b) WRITTEN POLICIES AND CRITERIA.—

1           (1) WRITTEN POLICIES.—A utilization review  
2       program shall be conducted consistent with written  
3       policies and procedures that govern all aspects of the  
4       program.

5           (2) USE OF WRITTEN CRITERIA.—

6               (A) IN GENERAL.—Such a program shall  
7       utilize written clinical review criteria developed  
8       pursuant to the program with the input of ap-  
9       propriate physicians. Such criteria shall include  
10      written clinical review criteria described in sec-  
11      tion 114(b)(4)(B).

12            (B) CONTINUING USE OF STANDARDS IN  
13      RETROSPECTIVE REVIEW.—If a health care  
14      service has been specifically pre-authorized or  
15      approved for a covered individual under such a  
16      program, the program shall not, pursuant to  
17      retrospective review, revise or modify the spe-  
18      cific standards, criteria, or procedures used for  
19      the utilization review for procedures, treatment,  
20      and services delivered to the individual during  
21      the same course of treatment.

22           (c) CONDUCT OF PROGRAM ACTIVITIES.—

23               (1) ADMINISTRATION BY HEALTH CARE PRO-  
24      FESSIONALS.—

1 (A) IN GENERAL.—A utilization review  
2 program shall be administered by qualified  
3 health care professionals who shall oversee re-  
4 view decisions.

5 (B) HEALTH CARE PROFESSIONAL DE-  
6 FINED.—In this section, the term “health care  
7 professional” means a physician or other health  
8 care practitioner licensed, accredited, or cer-  
9 tified to perform specified health services con-  
10 sistent with State law.

11 (2) USE OF QUALIFIED, INDEPENDENT PER-  
12 SONNEL.—

13 (A) IN GENERAL.—A utilization review  
14 program shall provide for the conduct of utiliza-  
15 tion review activities only through personnel  
16 who are qualified and, to the extent required,  
17 who have received appropriate training in the  
18 conduct of such activities under the program.

19 (B) PEER REVIEW OF SAMPLE OF AD-  
20 VERSE CLINICAL DETERMINATIONS.—Such a  
21 program shall provide that clinical peers (as de-  
22 fined in section 2(c)(2)) shall evaluate the clini-  
23 cal appropriateness of at least a sample of ad-  
24 verse clinical determinations.

1 (C) PROHIBITION OF CONTINGENT COM-  
2 PENSATION ARRANGEMENTS.—Such a program  
3 shall not, with respect to utilization review ac-  
4 tivities, permit or provide compensation or any-  
5 thing of value to its employees, agents, or con-  
6 tractors in a manner that—

7 (i) provides direct or indirect incen-  
8 tives for such persons to make inappropri-  
9 ate review decisions; or

10 (ii) is based, directly or indirectly, on  
11 the quantity or type of adverse determina-  
12 tions rendered.

13 (D) PROHIBITION OF CONFLICTS.—Such a  
14 program shall not permit a health care profes-  
15 sional who provides health care services to a  
16 covered individual to perform utilization review  
17 activities in connection with the health care  
18 services being provided to the individual. A  
19 group health plan, or a health insurance issuer  
20 in connection with the provision of health insur-  
21 ance coverage, may not retaliate against a cov-  
22 ered individual or health care provider based on  
23 such individual's or provider's use of, or partici-  
24 pation in, the utilization review program under  
25 this section.

1           (3) ACCESSIBILITY OF REVIEW.—Such a pro-  
2       gram shall provide that appropriate personnel per-  
3       forming utilization review activities under the pro-  
4       gram are reasonably accessible by toll-free telephone  
5       during normal business hours to discuss patient care  
6       and allow response to telephone requests, and that  
7       appropriate provision is made to receive and respond  
8       promptly to calls received during other hours.

9           (4) LIMITS ON FREQUENCY.—Such a program  
10      shall not provide for the performance of utilization  
11      review activities with respect to a class of services  
12      furnished to a covered individual more frequently  
13      than is reasonably required to assess whether the  
14      services under review are medically necessary or ap-  
15      propriate.

16          (5) LIMITATION ON INFORMATION REQUESTS.—  
17      Such a program shall provide that information shall  
18      be required to be provided by health care providers  
19      only to the extent it is necessary to perform the uti-  
20      lization review activity involved.

21          (6) REVIEW OF PRELIMINARY UTILIZATION RE-  
22      VIEW DECISION.—Such a program shall provide that  
23      a covered individual who is dissatisfied with a pre-  
24      liminary utilization review decision has the oppor-  
25      tunity to discuss the decision with, and have such

1 decision reviewed by, the medical director of the plan  
 2 or issuer involved (or the director's designee) who  
 3 has the authority to reverse the decision.

4 **SEC. 103. ESTABLISHMENT OF PROCESS FOR GRIEVANCES.**

5 (a) ESTABLISHMENT.—A group health plan, and a  
 6 health insurance issuer in connection with the provision  
 7 of health insurance coverage, shall provide meaningful  
 8 procedures for timely hearing and resolution of grievances  
 9 brought by covered individuals regarding any aspect of the  
 10 plan's or issuer's services, including a decision not to expe-  
 11 dite a coverage determination or reconsideration under  
 12 section 104(c)(4)(B)(ii)(II) or 105(c)(4)(B)(ii)(II).

13 (b) GUIDELINES.—The grievance procedures re-  
 14 quired under subsection (a) shall meet all guidelines estab-  
 15 lished by the appropriate Secretary.

16 (c) DISTINGUISHED FROM COVERAGE DETERMINA-  
 17 TIONS AND APPEALS.—The grievance procedures required  
 18 under subsection (a) shall be separate and distinct from  
 19 procedures regarding coverage determinations under sec-  
 20 tion 104 and reconsiderations under section 105 and ex-  
 21 ternal reviews by a qualified external appeal entity under  
 22 section 106 (which address appeals of coverage determina-  
 23 tions).

24 **SEC. 104. COVERAGE DETERMINATIONS.**

25 (a) REQUIREMENT.—

1           (1) RESPONSIBILITIES.—A group health plan,  
2           and a health insurance issuer in connection with the  
3           provision of health insurance coverage, shall estab-  
4           lish and maintain procedures for making timely cov-  
5           erage determinations (in accordance with the re-  
6           quirements of this section) regarding the benefits a  
7           covered individual is entitled to receive from the plan  
8           or issuer, including the amount of any copayments,  
9           deductibles, or other cost sharing applicable to such  
10          benefits. Under this section, the plan or issuer shall  
11          have a standard procedure for making such deter-  
12          minations, and procedures for expediting such deter-  
13          minations in cases in which application of the stand-  
14          ard deadlines could seriously jeopardize the covered  
15          individual's life, health, or ability to regain or main-  
16          tain maximum function or (in the case of a child  
17          under the age of 6) development.

18          (2) PARTIES WHO MAY REQUEST COVERAGE  
19          DETERMINATIONS.—Any of the following may re-  
20          quest a coverage determination relating to a covered  
21          individual and are parties to such determination:

22                (A) The covered individual.

23                (B) Any provider or other person acting on  
24                behalf of the covered individual with the indi-  
25                vidual's consent.

1           (3) EFFECT OF COVERAGE DETERMINATION.—

2           A coverage determination is binding on all parties  
3           unless it is reconsidered pursuant to section 105 or  
4           reviewed pursuant to section 106.

5           (b) NOTICE OF COVERAGE DETERMINATIONS.—

6           (1) IN GENERAL.—In the case of a request for  
7           a coverage determination, the group health plan or  
8           health insurance issuer shall provide notice pursuant  
9           to subsection (c) to the person submitting the re-  
10          quest of its determination as expeditiously as the  
11          health condition of the covered individual involved  
12          requires, but in no case later than deadline estab-  
13          lished under paragraph (2) or (3) (as the case may  
14          be) in the case of certain coverage determinations  
15          described in such paragraphs.

16          (2) DEADLINE FOR COVERAGE DETERMINA-  
17          TIONS INVOLVING PRIOR AUTHORIZATION SERVICES  
18          AND CONTINUED CARE.—In the case of a coverage  
19          determination described in section 101(a)(2)(A) in-  
20          volving the prior authorization of health care items  
21          and services for an individual or authorization for  
22          continued or extended health care services for an in-  
23          dividual, or additional services for an individual un-  
24          dergoing a course of continued treatment prescribed  
25          by a health care provider, the deadline established

under this paragraph is 3 business days after the date of receipt of information that is reasonably necessary to make such determination.

(3) DEADLINE FOR PREVIOUSLY PROVIDED SERVICES.—In the case of a coverage determination (as so described) involving retrospective review of health care services previously provided for an individual, the deadline established under this paragraph is 30 days of the date of receipt of information that is reasonably necessary to make such determination.

(c) NOTICE OF COVERAGE DETERMINATIONS.—

(1) REQUIREMENT.—

(A) IN GENERAL.—A group health plan or health insurance issuer that makes a coverage determination that—

(i) is completely favorable to the covered individual shall provide the party submitting the request for the coverage determination with notice of such determination; or

(ii) is adverse, in whole or in part, to the covered individual shall provide such party with written notice of the determination, including the information described in subparagraph (B).

1 (B) CONTENT OF WRITTEN NOTICE.—A  
2 written notice under subparagraph (A)(ii)  
3 shall—

4 (i) provide the specific reasons for the  
5 determination (including, in the case of a  
6 determination relating to utilization review,  
7 the clinical rationale for the determination)  
8 in clear and understandable language;

9 (ii) include notice, in clear and under-  
10 standable language, of the availability of  
11 the clinical review criteria relied upon in  
12 making the coverage determination;

13 (iii) describe, in clear and understand-  
14 able language, the reconsideration and re-  
15 view processes established to carry out sec-  
16 tions 105 and 106, including the right to,  
17 and conditions for, obtaining expedited  
18 consideration of requests for reconsider-  
19 ation or review; and

20 (iv) comply with any other require-  
21 ments specified by the appropriate Sec-  
22 retary.

23 (2) FAILURE TO PROVIDE TIMELY NOTICE.—  
24 Any failure of a group health plan or health insur-  
25 ance issuer to provide a covered individual with

1 timely notice of a coverage determination as speci-  
 2 fied in this section shall constitute an adverse cov-  
 3 erage determination and a timely request for a re-  
 4 consideration with respect to such determination  
 5 shall be deemed to have been made pursuant to the  
 6 section 105(a)(2).

7 (3) PROVISION OF ORAL NOTICE WITH WRIT-  
 8 TEN CONFIRMATION IN CASE OF EXPEDITED TREAT-  
 9 MENT.—If a group health plan or health insurance  
 10 issuer grants a request for expedited treatment  
 11 under subsection (c), the plan or issuer may first  
 12 provide notice of the coverage determination orally  
 13 within the deadlines established under subsection  
 14 (b)(3) and then shall mail written confirmation of  
 15 the determination within 2 business days of the date  
 16 of oral notification.

17 **SEC. 105. INTERNAL APPEALS (RECONSIDERATIONS).**

18 (a) REQUIREMENT.—

19 (1) RESPONSIBILITIES.—A group health plan,  
 20 and a health insurance issuer in connection with the  
 21 provision of health insurance coverage, shall estab-  
 22 lish and maintain procedures for making timely re-  
 23 considerations of coverage determinations in accord-  
 24 ance with this section. Under this section, the plan  
 25 or issuer shall have a standard procedure for making

1 such determinations, and procedures for expediting  
2 such determinations in cases in which application of  
3 the standard deadlines could seriously jeopardize the  
4 covered individual's life, health, or ability to regain  
5 or maintain maximum function or (in the case of a  
6 child under the age of 6) development.

7 (2) PARTIES WHO MAY REQUEST RECONSIDER-  
8 ATION.—Any party to a coverage determination may  
9 request a reconsideration of the determination under  
10 this section. Such party shall submit an oral or writ-  
11 ten request directly with the group health plan or  
12 health insurance issuer that made the determination.  
13 The party who files a request for reconsideration  
14 may withdraw it by filing a written request for with-  
15 drawal with the group health plan or health insur-  
16 ance issuer involved.

17 (3) DEADLINE FOR FILING REQUEST.—

18 (A) IN GENERAL.—Except as provided in  
19 subparagraph (B), a party to a coverage deter-  
20 mination shall submit the request for a recon-  
21 sideration within 60 calendar days from the  
22 date of the written notice of the coverage deter-  
23 mination.

24 (B) EXTENDING TIME FOR FILING RE-  
25 QUEST.—Such a party may submit a written re-

1           quest to the plan or issuer to extend the dead-  
2           line specified in subparagraph (A). If such a  
3           party demonstrates in the request for the exten-  
4           sion good cause for such extension, the plan or  
5           issuer may extend the deadline.

6           (4) PARTIES TO THE RECONSIDERATION.—

7                 (A) IN GENERAL.—The parties to the re-  
8           consideration are the parties to the coverage de-  
9           termination, as described in section 104(a)(2),  
10          and any other provider or entity (other than the  
11          plan or issuer) whose rights with respect to the  
12          coverage determination may be affected by the  
13          reconsideration (as determined by the entity  
14          that conducts the reconsideration).

15                (B) OPPORTUNITY TO SUBMIT EVI-  
16          DENCE.—A group health plan and a health in-  
17          surance issuer shall provide the parties to the  
18          reconsideration with a reasonable opportunity  
19          to present evidence and allegations of fact or  
20          law, related to the issue in dispute, in person as  
21          well as in writing. The plan or issuer shall in-  
22          form the parties of the conditions for submit-  
23          ting the evidence, especially any time limita-  
24          tions.

1           (5) EFFECT OF RECONSIDERATION.—A decision  
 2           of a plan or issuer after reconsideration is binding  
 3           on all parties unless it is reviewed pursuant to sec-  
 4           tion 106.

5           (6) LIMITATION ON CONDUCTING RECONSIDER-  
 6           ATION.—In conducting the reconsideration under  
 7           this subsection, the following rules shall apply:

8                   (A) The person or persons conducting the  
 9                   reconsideration shall not have been involved in  
 10                  making the underlying coverage determination  
 11                  that is the basis for such reconsideration.

12                  (B) If the issuer involved in the reconsider-  
 13                  ation is the plan’s or issuer’s denial of coverage  
 14                  based on a lack of medical necessity, a clinical  
 15                  peer (as defined in section 2(c)(2)) shall make  
 16                  the reconsidered determination.

17           (7) RECONSIDERATION DEFINED.—In this sub-  
 18           title, the term “reconsideration” means a review  
 19           under this section of a coverage determination that  
 20           is adverse to the covered individual involved, or of  
 21           the imposition of a limitation that is prohibited  
 22           under section 129, including a review of the evidence  
 23           and findings upon which it was based and any other  
 24           evidence the parties submit or the group health plan  
 25           or health insurance issuer obtains.

1 (b) DETERMINATION BY DEADLINE.—

2 (1) IN GENERAL.—In the case of a request for  
 3 a reconsideration, the group health plan or health  
 4 insurance issuer shall provide notice pursuant to  
 5 subsection (d) to the person submitting the request  
 6 of its determination as expeditiously as the health  
 7 condition of the covered individual involved requires,  
 8 but in no case later than the deadline established  
 9 under paragraph (2) or, if a request for expedited  
 10 treatment of a reconsideration is granted under sub-  
 11 section (c), the deadline established under paragraph  
 12 (3).

13 (2) STANDARD DEADLINE.—

14 (A) IN GENERAL.—The deadline estab-  
 15 lished under this paragraph is, subject to sub-  
 16 paragraph (B)—

17 (i) in the case of a reconsideration re-  
 18 garding a coverage determination described  
 19 in section 104(b)(2), 30 calendar days  
 20 after the date the plan or issuer receives  
 21 the request for the reconsideration, or

22 (ii) in other cases, 60 days after such  
 23 date.

1 (B) EXTENSION.—The plan or issuer may  
 2 extend the deadline under subparagraph (A) by  
 3 up to 14 calendar days if—

4 (i) the covered individual (or an au-  
 5 thorized representative of the individual)  
 6 requests the extension; or

7 (ii) the plan or issuer justifies to the  
 8 applicable authority a need for additional  
 9 information to make the reconsideration  
 10 and how the delay is in the interest of the  
 11 covered individual.

12 (3) EXPEDITED TREATMENT DEADLINE.—

13 (A) IN GENERAL.—The deadline estab-  
 14 lished under this paragraph is, subject to sub-  
 15 paragraphs (B) and (C), 72 hours after the  
 16 date the plan or issuer receives the request for  
 17 the expedited treatment under subsection (d).

18 (B) EXTENSION.—The plan or issuer may  
 19 extend the deadline under subparagraph (A) by  
 20 up to 5 calendar days if—

21 (i) the covered individual (or an au-  
 22 thorized representative of the individual)  
 23 requests the extension; or

24 (ii) the plan or issuer justifies to the  
 25 applicable authority a need for additional

1 information to make the reconsideration  
 2 and how the delay is in the interest of the  
 3 covered individual.

4 (C) HOW INFORMATION FROM NON-  
 5 PARTICIPATING PROVIDERS AFFECTS DEAD-  
 6 LINES FOR EXPEDITED RECONSIDERATIONS.—

7 In the case of a group health plan or health in-  
 8 surance issuer that requires medical informa-  
 9 tion from nonparticipating providers in order to  
 10 make a reconsideration, the deadline specified  
 11 under subparagraph (A) shall begin when the  
 12 plan or issuer receives such information. Non-  
 13 participating providers shall make reasonable  
 14 and diligent efforts to expeditiously gather and  
 15 forward all necessary information to the plan or  
 16 issuer in order to receive timely payment.

17 (c) EXPEDITED TREATMENT.—

18 (1) REQUEST FOR EXPEDITED TREATMENT.—A  
 19 covered individual (or an authorized representative  
 20 of the individual) may request that the plan or  
 21 issuer expedite a reconsideration involving the issues  
 22 described in section 101(a)(2).

23 (2) WHO MAY REQUEST.—To request expedited  
 24 treatment of a reconsideration, a covered individual  
 25 (or an authorized representative of the individual)

1       shall submit an oral or written request directly to  
2       the plan or issuer (or, if applicable, to the entity  
3       that the plan or issuer has designated as responsible  
4       for making the decision relating to the reconsider-  
5       ation).

6               (3) PROVIDER SUPPORT.—

7               (A) IN GENERAL.—A physician or other  
8       health care provider may provide oral or written  
9       support for a request for expedited treatment  
10      under this subsection.

11              (B) PROHIBITION OF PUNITIVE ACTION.—

12      A group health plan and a health insurance  
13      issuer in connection with the provision of health  
14      insurance coverage shall not take or threaten to  
15      take any punitive action against a physician or  
16      other health care provider acting on behalf or  
17      in support of a covered individual seeking expe-  
18      dited treatment under this subsection.

19              (4) PROCESSING OF REQUESTS.—A group  
20      health plan and a health insurance issuer in connec-  
21      tion with the provision of health insurance coverage  
22      shall establish and maintain the following procedures  
23      for processing requests for expedited treatment of  
24      reconsiderations:

1 (A) An efficient and convenient means for  
2 the submission of oral and written requests for  
3 expedited treatment. The plan or issuer shall  
4 document all oral requests in writing and main-  
5 tain the documentation in the case file of the  
6 covered individual involved.

7 (B) A means for deciding promptly wheth-  
8 er to expedite a reconsideration, based on the  
9 following requirements:

10 (i) For a request made or supported  
11 by a physician, the plan or issuer shall ex-  
12 pedite the reconsideration if the physician  
13 indicates that applying the standard dead-  
14 line under subsection (b)(2) for making the  
15 reconsideration determination could seri-  
16 ously jeopardize the covered individual's  
17 life, health, or ability to regain or maintain  
18 maximum function or (in the case of a  
19 child under the age of 6) development.

20 (ii) For another request, the plan or  
21 issuer shall expedite the reconsideration if  
22 the plan or issuer determines that applying  
23 such standard deadline for making the re-  
24 consideration determination could seriously  
25 jeopardize the covered individual's life,

1 health, or ability to regain or maintain  
 2 maximum function or (in the case of a  
 3 child under the age of 6) development.

4 (5) ACTIONS FOLLOWING DENIAL OF REQUEST  
 5 FOR EXPEDITED TREATMENT.—If a group health  
 6 plan or a health insurance issuer in connection with  
 7 the provision of health insurance coverage denies a  
 8 request for expedited treatment of a reconsideration  
 9 under this subsection, the plan or issuer shall—

10 (A) make the reconsideration determina-  
 11 tion within the standard deadline otherwise ap-  
 12 plicable; and

13 (B) provide the individual submitting the  
 14 request with—

15 (i) prompt oral notice of the denial of  
 16 the request, and

17 (ii) within 2 business days a written  
 18 notice that—

19 (I) explains that the plan or  
 20 issuer will process the reconsideration  
 21 request within the standard deadlines;

22 (II) informs the requester of the  
 23 right to file a grievance if the re-  
 24 quester disagrees with the plan's or

1 issuer's decision not to expedite the  
2 reconsideration; and

3 (III) provides instructions about  
4 the grievance process and its time-  
5 frames.

6 (6) ACTION ON ACCEPTED REQUEST FOR EXPE-  
7 DITED TREATMENT.—If a group health plan or  
8 health insurance issuer grants a request for expe-  
9 dited treatment of a reconsideration, the plan or  
10 issuer shall make the reconsideration determination  
11 and provide the notice under subsection (d) within  
12 the deadlines specified under subsection (b)(3).

13 (d) NOTICE OF DECISION IN RECONSIDERATIONS.—

14 (1) REQUIREMENT.—

15 (A) IN GENERAL.—A group health plan or  
16 health insurance issuer that makes a decision in  
17 the reconsideration that—

18 (i) is completely favorable to the cov-  
19 ered individual shall provide the party sub-  
20 mitting the request for the reconsideration  
21 with notice of such decision; or

22 (ii) is adverse, in whole or in part, to  
23 the covered individual shall—

24 (I) provide such party with writ-  
25 ten notice of the decision, including

1 the information described in subpara-  
2 graph (B), and

3 (II) prepare the case file (includ-  
4 ing such notice) for the covered indi-  
5 vidual involved, to be available for  
6 submission (if requested) under sec-  
7 tion 106(a).

8 (B) CONTENT OF WRITTEN NOTICE.—The  
9 written notice under subparagraph (A)(ii)(I)  
10 shall—

11 (i) provide the specific reasons for the  
12 decision in the reconsideration (including,  
13 in the case of a decision relating to utiliza-  
14 tion review, the clinical rationale for the  
15 decision) in clear and understandable lan-  
16 guage;

17 (ii) include notice of the availability of  
18 the clinical review criteria relied upon in  
19 making the decision;

20 (iii) describe the review processes es-  
21 tablished to carry out sections 106, includ-  
22 ing the right to, and conditions for, obtain-  
23 ing expedited consideration of requests for  
24 review under such section; and

1 (iv) comply with any other require-  
2 ments specified by the appropriate Sec-  
3 retary.

4 (2) FAILURE TO PROVIDE TIMELY NOTICE.—  
5 Any failure of a group health plan or health insur-  
6 ance issuer to provide a covered individual with  
7 timely notice of a decision in a reconsideration as  
8 specified in this section shall constitute an affirma-  
9 tion of the adverse coverage determination and the  
10 plan or issuer shall submit the case file to the quali-  
11 fied external appeal entity under section 106 within  
12 24 hours of expiration of the deadline otherwise ap-  
13 plicable.

14 (3) PROVISION OF ORAL NOTICE WITH WRIT-  
15 TEN CONFIRMATION IN CASE OF EXPEDITED TREAT-  
16 MENT.—If a group health plan or health insurance  
17 issuer grants a request for expedited treatment  
18 under subsection (c), the plan or issuer may first  
19 provide notice of the decision in the reconsideration  
20 orally within the deadlines established under sub-  
21 section (b)(3) and then shall mail written confirma-  
22 tion of the decision within 2 business days of the  
23 date of oral notification.

24 (4) AFFIRMATION OF AN ADVERSE COVERAGE  
25 DETERMINATION UNDER EXPEDITED TREATMENT.—

1 If, as a result of its reconsideration, the plan or  
 2 issuer affirms, in whole or in part, a coverage deter-  
 3 mination that is adverse to the covered individual  
 4 and the reconsideration received expedited treatment  
 5 under subsection (c), the plan or issuer shall submit  
 6 the case file (including the written notice of the deci-  
 7 sion in the reconsideration) to the qualified external  
 8 appeal entity as expeditiously as the covered individ-  
 9 ual's health condition requires, but in no case later  
 10 than within 24 hours of its affirmation. The plan or  
 11 issuer shall make reasonable and diligent efforts to  
 12 assist in gathering and forwarding information to  
 13 the qualified external appeal entity.

14 (5) NOTIFICATION OF INDIVIDUAL.—If the plan  
 15 or issuer refers the matter to an qualified external  
 16 appeal entity under paragraph (2) or (4), it shall  
 17 concurrently notify the individual (or an authorized  
 18 representative of the individual) of that action.

19 **SEC. 106. EXTERNAL APPEALS (REVIEWS).**

20 (a) REVIEW BY QUALIFIED EXTERNAL APPEAL EN-  
 21 TITY.—

22 (1) IN GENERAL.—If a qualified external appeal  
 23 entity obtains a case file under section 105(d) or  
 24 under paragraph (2) and determines that such ap-  
 25 peal is not so supported but—

1 (A) there is a significant financial amount  
 2 in controversy (as defined by the Secretary); or

3 (B) the appeal involves services for the di-  
 4 agnosis, treatment, or management of an ill-  
 5 ness, disability, or condition which the entity  
 6 finds, in accordance with standards established  
 7 by the entity and approved by the Secretary,  
 8 constitutes a condition that could seriously  
 9 jeopardize the covered individual's life, health,  
 10 or ability to regain or maintain maximum func-  
 11 tion or (in the case of a child under the age of  
 12 6) development;

13 the entity shall review and resolve under this section  
 14 any remaining issues in dispute.

15 (2) REQUEST FOR REVIEW.—

16 (A) IN GENERAL.—A party to a reconsid-  
 17 ered determination under section 105 that re-  
 18 ceives notice of an unfavorable determination  
 19 under section 105(d) may request a review of  
 20 such determination by a qualified external ap-  
 21 peal entity under this section.

22 (B) TIME FOR REQUEST.—To request such  
 23 a review, such party shall submit an oral or  
 24 written request directly to the plan or issuer  
 25 (or, if applicable, to the entity that the plan or

1 issuer has designated as responsible for making  
2 the determination).

3 (C) IF REVIEW IS REQUESTED.—If a party  
4 provides the plan or issuer (or such an entity)  
5 with notice of a request for such review, the  
6 plan or issuer (or such entity) shall submit the  
7 case file to the qualified external appeal entity  
8 as expeditiously as the covered individual’s  
9 health condition requires, but in no case later  
10 than 2 business days from the date the plan or  
11 issuer (or entity) receives such request. The  
12 plan or issuer (or entity) shall make reasonable  
13 and diligent efforts to assist in gathering and  
14 forwarding information to the qualified external  
15 appeal entity.

16 (3) NOTICE AND TIMING FOR REVIEW.—The  
17 qualified external appeal entity shall establish and  
18 apply rules for the timing and content of notices for  
19 reviews under this section (including appropriate ex-  
20 pedited treatment of reviews under this section) that  
21 are similar to the applicable requirements for timing  
22 and content of notices in the case of reconsiderations  
23 under subsections (b), (c), and (d) of section 105.

24 (4) PARTIES.—The parties to the review by a  
25 qualified external appeal entity under this section

1 shall be the same parties listed in section 105(a)(4)  
 2 who qualified during the plan's or issuer's reconsid-  
 3 eration, with the addition of the plan or issuer.

4 (b) GENERAL ELEMENTS OF EXTERNAL APPEALS.—

5 (1) CONTRACT WITH QUALIFIED EXTERNAL AP-  
 6 PEAL ENTITY.—

7 (A) CONTRACT REQUIREMENT.—Subject to  
 8 subparagraph (B), the external appeal review  
 9 under this section of a determination of a plan  
 10 or issuer shall be conducted under a contract  
 11 between the plan or issuer and 1 or more quali-  
 12 fied external appeal entities.

13 (B) ELIGIBILITY FOR DESIGNATION AS EX-  
 14 TERNAL REVIEW ENTITY.—Entities eligible to  
 15 conduct reviews brought under this subsection  
 16 shall include—

17 (i) any State licensed or credentialed  
 18 external review entity;

19 (ii) a State agency established for the  
 20 purpose of conducting independent exter-  
 21 nal reviews; and

22 (iii) an independent, external entity  
 23 that contracts with the appropriate Sec-  
 24 retary.

25 (C) LICENSING AND CREDENTIALING.—

1 (i) IN GENERAL.—In licensing or  
 2 credentialing entities described in subpara-  
 3 graph (B)(i), the State agent shall use li-  
 4 censing and certification procedures devel-  
 5 oped by the State in consultation with the  
 6 National Association of Insurance Commis-  
 7 sioners.

8 (ii) SPECIAL RULE.—In the case of a  
 9 State that—

10 (I) has not established such li-  
 11 censing or credentialing procedures  
 12 within 24 months of the date of enact-  
 13 ment of this Act, the State shall li-  
 14 cense or credential such entities in ac-  
 15 cordance with procedures developed by  
 16 the Secretary; or

17 (II) refuses to designate such en-  
 18 tities, the Secretary shall license or  
 19 credential such entities.

20 (D) QUALIFICATIONS.—An entity (which  
 21 may be a governmental entity) shall meet the  
 22 following requirements in order to be a qualified  
 23 external appeal entity:

24 (i) There is no real or apparent con-  
 25 flict of interest that would impede the en-

tity from conducting external appeal activities independent of the plan or issuer.

(ii) The entity conducts external appeal activities through clinical peers (as defined in section 2(c)(2)).

(iii) The entity has sufficient medical, legal, and other expertise and sufficient staffing to conduct external appeal activities for the plan or issuer on a timely basis consistent with subsection (a)(3).

(iv) The entity meets such other requirements as the appropriate Secretary may impose.

(E) LIMITATION ON PLAN OR ISSUER SELECTION.—If an applicable authority permits more than 1 entity to qualify as a qualified external appeal entity with respect to a group health plan or health insurance issuer and the plan or issuer may select among such qualified entities, the applicable authority—

(i) shall assure that the selection process will not create any incentives for qualified external appeal entities to make a decision in a biased manner; and

1 (ii) shall implement procedures for au-  
 2 diting a sample of decisions by such enti-  
 3 ties to assure that no such decisions are  
 4 made in a biased manner.

5 (F) OTHER TERMS AND CONDITIONS.—

6 The terms and conditions of a contract under  
 7 this paragraph shall be consistent with the  
 8 standards the appropriate Secretary shall estab-  
 9 lish to assure that there is no real or apparent  
 10 conflict of interest in the conduct of external  
 11 appeal activities. Such contract shall provide  
 12 that the direct costs of the process (not includ-  
 13 ing costs of representation of a covered individ-  
 14 ual or other party) shall be paid by the plan or  
 15 issuer, and not by the covered individual.

16 (2) ELEMENTS OF PROCESS.—An external ap-  
 17 peal process under this section shall be conducted  
 18 consistent with standards established by the appro-  
 19 priate Secretary that include at least the following:

20 (A) FAIR PROCESS; DE NOVO DETERMINA-  
 21 TION.—The process shall provide for a fair, de  
 22 novo determination.

23 (B) OPPORTUNITY TO SUBMIT EVIDENCE,  
 24 HAVE REPRESENTATION, AND MAKE ORAL

PRESENTATION.—Any party to a review under this section—

(i) may submit and review evidence related to the issues in dispute,

(ii) may use the assistance or representation of 1 or more individuals (any of whom may be an attorney), and

(iii) may make an oral presentation.

(C) PROVISION OF INFORMATION.—The plan or issuer involved shall provide timely access to all its records relating to the matter being reviewed under this section and to all provisions of the plan or health insurance coverage (including any coverage manual) relating to the matter.

(3) ADMISSIBLE EVIDENCE.—In addition to personal health and medical information supplied with respect to an individual whose claim for benefits has been appealed and the opinion of the individual's treating physician or health care professional, an external appeals entity shall take into consideration the following evidence:

(A) The results of studies that meet professionally recognized standards of validity and

1 replicability or that have been published in  
2 peer-reviewed journals.

3 (B) The results of professional consensus  
4 conferences conducted or financed in whole or  
5 in part by one or more government agencies.

6 (C) Practice and treatment guidelines pre-  
7 pared or financed in whole or in part by govern-  
8 ment agencies.

9 (D) Government-issued coverage and treat-  
10 ment policies.

11 (E) To the extent that the entity deter-  
12 mines it to be free of any conflict of interest—

13 (i) the opinions of individuals who are  
14 qualified as experts in one or more fields  
15 of health care which are directly related to  
16 the matters under appeal, and

17 (ii) the results of peer reviews con-  
18 ducted by the plan or issuer involved.

19 (c) NOTICE OF DETERMINATION BY EXTERNAL AP-  
20 PEAL ENTITY.—

21 (1) RESPONSIBILITY FOR THE NOTICE.—After  
22 the qualified external appeal entity has reviewed and  
23 resolved the determination that has been appealed,  
24 such entity shall mail a notice of its final decision  
25 to the parties.

1 (2) CONTENT OF THE NOTICE.—The notice de-  
 2 scribed in paragraph (1) shall—

3 (A) describe the specific reasons for the  
 4 entity's decisions; and

5 (B) comply with any other requirements  
 6 specified by the appropriate Secretary.

7 (d) EFFECT OF DETERMINATION.—A final decision  
 8 by the qualified external appeal entity after a review of  
 9 the determination that has been appealed is final and  
 10 binding on the group health plan or the health insurance  
 11 issuer.

## 12 **Subtitle B—Consumer Information**

### 13 **SEC. 111. HEALTH PLAN INFORMATION.**

14 (a) DISCLOSURE REQUIREMENT.—

15 (1) GROUP HEALTH PLANS.—A group health  
 16 plan shall—

17 (A) provide to participants and bene-  
 18 ficiaries at the time of initial coverage under  
 19 the plan (or the effective date of this section, in  
 20 the case of individuals who are participants or  
 21 beneficiaries as of such date), at least annually  
 22 thereafter, and at the beginning of any open en-  
 23 rollment period provided under the plan, the in-  
 24 formation described in subsection (b) in printed  
 25 form;

1           (B) provide to participants and bene-  
 2           ficiaries information in printed form on mate-  
 3           rial changes in the information described in  
 4           paragraphs (1), (2)(A), (2)(B), (3)(A), (6), and  
 5           (7) of subsection (b), or a change in the health  
 6           insurance issuer through which coverage is pro-  
 7           vided, within a reasonable period of (as speci-  
 8           fied by the Secretary, but not later than 30  
 9           days after) the effective date of the changes;  
 10          and

11           (C) upon request, make available to par-  
 12           ticipants and beneficiaries, the applicable au-  
 13           thority, and prospective participants and bene-  
 14           ficiaries, the information described in sub-  
 15           sections (b) and (c) in printed form.

16          (2) HEALTH INSURANCE ISSUERS.—A health  
 17          insurance issuer in connection with the provision of  
 18          health insurance coverage shall—

19           (A) provide to individuals enrolled under  
 20           such coverage at the time of enrollment, and at  
 21           least annually thereafter, (and to plan adminis-  
 22           trators of group health plans in connection with  
 23           which such coverage is offered) the information  
 24           described in subsection (b) in printed form;

1 (B) provide to enrollees and such plan ad-  
 2 ministrators information in printed form on  
 3 material changes in the information described  
 4 in paragraphs (1), (2)(A), (2)(B), (3)(A), (6),  
 5 and (7) of subsection (b), or a change in the  
 6 health insurance issuer through which coverage  
 7 is provided, within a reasonable period of (as  
 8 specified by the Secretary, but not later than  
 9 30 days after) the effective date of the changes;  
 10 and

11 (C) upon request, make available to the  
 12 applicable authority, to individuals who are pro-  
 13 spective enrollees, to plan administrators of  
 14 group health plans that may obtain such cov-  
 15 erage, and to the public the information de-  
 16 scribed in subsections (b) and (c) in printed  
 17 form.

18 (3) EXEMPTION AUTHORITY.—Upon application  
 19 of one or more group health plans or health insur-  
 20 ance issuers, the appropriate Secretary, under proce-  
 21 dures established by such Secretary, may grant an  
 22 exemption to one or more plans or issuers from com-  
 23 pliance with one or more of the requirements of  
 24 paragraph (1) or (2). Such an exemption may be  
 25 granted for plans and issuers as a class with similar

1 characteristics, such as private fee-for-service plans  
 2 described in section 1859(b)(2) of the Social Secu-  
 3 rity Act.

4 (4) ESTABLISHMENT OF INTERNET SITE.—The  
 5 appropriate Secretaries shall provide for the estab-  
 6 lishment of 1 or more sites on the Internet to pro-  
 7 vide technical support and information concerning  
 8 the rights of participants, beneficiaries, and enrollees  
 9 under this title.

10 (b) INFORMATION PROVIDED.—The information de-  
 11 scribed in this subsection with respect to a group health  
 12 plan or health insurance coverage offered by a health in-  
 13 surance issuer includes the following:

14 (1) SERVICE AREA.—The service area of the  
 15 plan or issuer.

16 (2) BENEFITS.—Benefits offered under the  
 17 plan or coverage, including—

18 (A) covered benefits, including benefits for  
 19 preventive services, benefit limits, and coverage  
 20 exclusions, any optional supplemental benefits  
 21 under the plan or coverage and the terms and  
 22 conditions (including premiums or cost-sharing)  
 23 for such supplemental benefits, and any out-of-  
 24 area coverage;

(B) cost sharing, such as premiums, deductibles, coinsurance, and copayment amounts, including any liability for balance billing, any maximum limitations on out of pocket expenses, and the maximum out of pocket costs for services that are provided by nonparticipating providers or that are furnished without meeting the applicable utilization review requirements;

(C) the extent to which benefits may be obtained from nonparticipating providers, and any supplemental premium or cost-sharing in so obtaining such benefits;

(D) the extent to which a participant, beneficiary, or enrollee may select from among participating providers and the types of providers participating in the plan or issuer network;

(E) process for determining experimental coverage or coverage in cases of investigational treatments and clinical trials; and

(F) use of a prescription drug formulary.

(3) ACCESS.—A description of the following:

(A) The number, mix, and distribution of health care providers under the plan or coverage.

1           (B) The procedures for participants, bene-  
2           ficiaries, and enrollees to select, access, and  
3           change participating primary and specialty pro-  
4           viders.

5           (C) The rights and procedures for obtain-  
6           ing referrals (including standing referrals) to  
7           participating and nonparticipating providers.

8           (D) Any limitations imposed on the selec-  
9           tion of qualifying participating health care pro-  
10          viders, including any limitations imposed under  
11          section 122(a)(2)(B).

12          (E) How the plan or issuer addresses the  
13          needs of participants, beneficiaries, and enroll-  
14          ees and others who do not speak English or  
15          who have other special communications needs in  
16          accessing providers under the plan or coverage,  
17          including the provision of information described  
18          in this subsection and subsection (c) to such in-  
19          dividuals, including the provision of information  
20          in a language other than English if 5 percent  
21          of the number of participants, beneficiaries, and  
22          enrollees communicate in that language instead  
23          of English, and including the availability of in-  
24          terpreters, audio tapes, and information in

1           braille to meet the needs of people with special  
2           communications needs.

3           (4) OUT-OF-AREA COVERAGE.—Out-of-area cov-  
4           erage provided by the plan or issuer.

5           (5) EMERGENCY COVERAGE.—Coverage of  
6           emergency services, including—

7                   (A) the appropriate use of emergency serv-  
8                   ices, including use of the 911 telephone system  
9                   or its local equivalent in emergency situations  
10                  and an explanation of what constitutes an  
11                  emergency situation;

12                  (B) the process and procedures of the plan  
13                  or issuer for obtaining emergency services; and

14                  (C) the locations of (i) emergency depart-  
15                  ments, and (ii) other settings, in which plan  
16                  physicians and hospitals provide emergency  
17                  services and post-stabilization care.

18           (6) PRIOR AUTHORIZATION RULES.—Rules re-  
19           garding prior authorization or other review require-  
20           ments that could result in noncoverage or non-  
21           payment.

22           (7) GRIEVANCE AND APPEALS PROCEDURES.—  
23           All appeal or grievance rights and procedures under  
24           the plan or coverage, including the method for filing  
25           grievances and the time frames and circumstances

1 for acting on grievances and appeals, the name, ad-  
2 dress, and telephone number of the applicable au-  
3 thority with respect to the plan or issuer, and the  
4 availability of assistance through an ombudsman to  
5 individuals in relation to group health plans and  
6 health insurance coverage.

7 (8) QUALITY ASSURANCE.—A summary descrip-  
8 tion of the data on quality indicators and measures  
9 submitted under section 112(a) for the plan or  
10 issuer, including a summary description of the data  
11 on process and outcome satisfaction of participants,  
12 beneficiaries, and enrollees (including data on indi-  
13 vidual voluntary disenrollment and grievances and  
14 appeals) described in section 112(b)(3)(D), and no-  
15 tice that information comparing such indicators and  
16 measures for different plans and issuers is available  
17 through the Agency for Health Care Policy and Re-  
18 search.

19 (9) SUMMARY OF PROVIDER FINANCIAL INCEN-  
20 TIVES.—A summary description of the information  
21 on the types of financial payment incentives (de-  
22 scribed in section 1852(j)(4) of the Social Security  
23 Act) provided by the plan or issuer under the cov-  
24 erage.

1           (10) INFORMATION ON ISSUER.—Notice of ap-  
2           propriate mailing addresses and telephone numbers  
3           to be used by participants, beneficiaries, and enroll-  
4           ees in seeking information or authorization for treat-  
5           ment.

6           (11) INFORMATION ON LICENSURE.—Informa-  
7           tion on the licensure, certification, or accreditation  
8           status of the plan or issuer.

9           (12) AVAILABILITY OF TECHNICAL SUPPORT  
10          AND INFORMATION.—Notice that technical support  
11          and information concerning the rights of partici-  
12          pants, beneficiaries, and enrollees under this title are  
13          available from the Secretary of Labor (in the case  
14          of group health plans) or the Secretary of Health  
15          and Human Services (in the case of health insurance  
16          issuers), including the telephone numbers and mail-  
17          ing address of the regional offices of the appropriate  
18          Secretary and the Internet address to obtain such  
19          information and support.

20          (13) ADVANCE DIRECTIVES AND ORGAN DONA-  
21          TION DECISIONS.—Information regarding the use of  
22          advance directives and organ donation decisions  
23          under the plan or coverage.

24          (14) PARTICIPATING PROVIDER LIST.—A list of  
25          current participating health care providers for the

1 relevant geographic area, including the name, ad-  
 2 dress and telephone number of each provider.

3 (15) AVAILABILITY OF INFORMATION ON RE-  
 4 QUEST.—Notice that the information described in  
 5 subsection (c) is available upon request and how and  
 6 where (such as the telephone number and Internet  
 7 website) such information may be obtained.

8 (c) INFORMATION MADE AVAILABLE UPON RE-  
 9 QUEST.—The information described in this subsection is  
 10 the following:

11 (1) UTILIZATION REVIEW ACTIVITIES.—A de-  
 12 scription of procedures used and requirements (in-  
 13 cluding circumstances, time frames, and appeal  
 14 rights) under any utilization review program under  
 15 section 102(a), including under any drug formulary  
 16 program under section 123(b).

17 (2) GRIEVANCE AND APPEALS INFORMATION.—  
 18 Information on the number of grievances and inter-  
 19 nal and external appeals and on the disposition in  
 20 the aggregate of such matters, including information  
 21 on the reasons for the disposition of external appeal  
 22 cases.

23 (3) METHOD OF COMPENSATION.—A summary  
 24 description as to the method of compensation of par-  
 25 ticipating health care professionals and health care

1 facilities, including information on the types of fi-  
 2 nancial payment incentives (described in section  
 3 1852(j)(4) of the Social Security Act) provided by  
 4 the plan or issuer under the coverage and on the  
 5 proportion of participating health care professionals  
 6 who are compensated under each type of incentive  
 7 under the plan or coverage.

8 (4) CONFIDENTIALITY POLICIES AND PROCE-  
 9 DURES.—A description of the policies and proce-  
 10 dures established to carry out section 112.

11 (5) FORMULARY RESTRICTIONS.—A description  
 12 of the nature of any drug formula restrictions, in-  
 13 cluding the specific prescription medications in-  
 14 cluded in any formulary and any provisions for ob-  
 15 taining off-formulary medications.

16 (6) ADDITIONAL INFORMATION ON PARTICIPAT-  
 17 ING PROVIDERS.—For each current participating  
 18 health care provider described in subsection  
 19 (b)(14)—

20 (A) the licensure or accreditation status of  
 21 the provider;

22 (B) to the extent possible, an indication of  
 23 whether the provider is available to accept new  
 24 patients;

1 (C) in the case of medical personnel, the  
 2 education, training, speciality qualifications or  
 3 certification, speciality focus, affiliation ar-  
 4 rangements, and specialty board certification (if  
 5 any) of the provider; and

6 (D) any measures of consumer satisfaction  
 7 and quality indicators for the provider.

8 (7) PERCENTAGE OF PREMIUMS USED FOR  
 9 BENEFITS (LOSS-RATIOS).—In the case of health in-  
 10 surance coverage only (and not with respect to group  
 11 health plans that do not provide coverage through  
 12 health insurance coverage), a description of the over-  
 13 all loss-ratio for the coverage (as defined in accord-  
 14 ance with rules established or recognized by the Sec-  
 15 retary of Health and Human Services).

16 (8) QUALITY INFORMATION DEVELOPED.—  
 17 Quality information on processes and outcomes de-  
 18 veloped as part of an accreditation or licensure proc-  
 19 ess for the plan or issuer to the extent the informa-  
 20 tion is publicly available.

21 (d) FORM OF DISCLOSURE.—

22 (1) UNIFORMITY.—Information required to be  
 23 disclosed under this section shall be provided in ac-  
 24 cordance with uniform, national reporting standards  
 25 specified by the Secretary, after consultation with

1 applicable State authorities, so that prospective en-  
2 rollees may compare the attributes of different  
3 issuers and coverage offered within an area within a  
4 type of coverage. Such information shall be provided  
5 in an accessible format that is understandable to the  
6 average participant, beneficiary, or enrollee involved.

7 (2) INFORMATION INTO HANDBOOK.—Nothing  
8 in this section shall be construed as preventing a  
9 group health plan or health insurance issuer from  
10 making the information under subsections (b) and  
11 (c) available to participants, beneficiaries, and en-  
12 rollees through an enrollee handbook or similar pub-  
13 lication.

14 (3) UPDATING PARTICIPATING PROVIDER IN-  
15 FORMATION.—The information on participating  
16 health care providers described in subsections  
17 (b)(14) and (c)(6) shall be updated within such rea-  
18 sonable period as determined appropriate by the  
19 Secretary. A group health plan or health insurance  
20 issuer shall be considered to have complied with the  
21 provisions of such subsection if the plan or issuer  
22 provides the directory or listing of participating pro-  
23 viders to participants and beneficiaries or enrollees  
24 once a year and such directory or listing is updated  
25 within such a reasonable period to reflect any mate-

1       rial changes in participating providers. Nothing in  
 2       this section shall prevent a plan or issuer from  
 3       changing or updating other information made avail-  
 4       able under this section.

5           (4) RULE OF MAILING TO LAST ADDRESS.—For  
 6       purposes of this section, a plan or issuer, in reliance  
 7       on records maintained by the plan or issuer, shall be  
 8       deemed to have met the requirements of this section  
 9       with respect to the disclosure of information to a  
 10      participant, beneficiary, or enrollee if the plan or  
 11      issuer transmits the information requested to the  
 12      participant, beneficiary, or enrollee at the address  
 13      contained in such records with respect to such par-  
 14      ticipant, beneficiary, or enrollee.

15      (e) ENROLLEE ASSISTANCE.—

16           (1) IN GENERAL.—Each State that obtains a  
 17      grant under paragraph (3) shall provide for creation  
 18      and operation of a Health Insurance Ombudsman  
 19      through a contract with a not-for-profit organization  
 20      that operates independent of group health plans and  
 21      health insurance issuers. Such Ombudsman shall be  
 22      responsible for at least the following:

23           (A) To provide consumers in the State  
 24      with information about health insurance cov-

1           erage options or coverage options offered within  
2           group health plan.

3           (B) To provide counseling and assistance  
4           to enrollees dissatisfied with their treatment by  
5           health insurance issuers and group health plans  
6           in regard to such coverage or plans and with re-  
7           spect to grievances and appeals regarding deter-  
8           minations under such coverage or plans.

9           (2) FEDERAL ROLE.—In the case of any State  
10          that does not provide for such an Ombudsman under  
11          paragraph (1), the Secretary may provide for the  
12          creation and operation of a Health Insurance Om-  
13          budsman through a contract with a not-for-profit or-  
14          ganization that operates independent of group health  
15          plans and health insurance issuers and that is to  
16          provide consumers in the State with information  
17          about health insurance coverage options or coverage  
18          options offered within group health plans.

19          (3) ELIGIBILITY.—To be eligible to serve as a  
20          Health Insurance Ombudsman under this section, a  
21          not-for-profit organization shall provide assurances  
22          that—

23                 (A) the organization has no real or per-  
24                 ceived conflict of interest in providing advice

1           and assistance to consumers regarding health  
2           insurance coverage, and

3           (B) the organization is independent of  
4           health insurance issuers, health care providers,  
5           health care payors, and regulators of health  
6           care or health insurance.

7           (4) AUTHORIZATION OF APPROPRIATIONS.—  
8           There are authorized to be appropriated to the Sec-  
9           retary of Health and Human Services such amounts  
10          as may be necessary to provide for grants to States  
11          for contracts for Health Insurance Ombudsmen  
12          under paragraph (1) or contracts for such Ombuds-  
13          men under paragraph (2).

14          (5) CONSTRUCTION.—Nothing in this section  
15          shall be construed to prevent the use of other forms  
16          of enrollee assistance.

17          (f) CONSTRUCTION.—Nothing in this section shall be  
18          construed as requiring public disclosure of individual con-  
19          tracts or financial arrangements between a group health  
20          plan or health insurance issuer and any provider.

21   **SEC. 112. HEALTH CARE QUALITY INFORMATION.**

22          (a) COLLECTION AND SUBMISSION OF INFORMATION  
23          ON QUALITY INDICATORS AND MEASURES.—

24                (1) IN GENERAL.—A group health plan and a  
25          health insurance issuer that offers health insurance

1 coverage shall collect and submit to the Director for  
 2 the Agency for Health Care Policy and Research (in  
 3 this section referred to as the “Director”) aggregate  
 4 data on quality indicators and measures (as defined  
 5 in subsection (g)) that includes the minimum uni-  
 6 form data set specified under subsection (b). Such  
 7 data shall not include patient identifiers.

8 (2) DATA SAMPLING METHODS.—The Director  
 9 shall develop data sampling methods for the collec-  
 10 tion of data under this subsection.

11 (3) EXEMPTION AUTHORITY.—The provisions  
 12 of section 111(a)(3) shall apply to the requirements  
 13 of paragraph (1) in the same manner as they apply  
 14 to the requirements referred to in such section.

15 (b) MINIMUM UNIFORM DATA SET.—

16 (1) IN GENERAL.—The Secretary shall specify  
 17 (and may from time to time update) by rule the data  
 18 required to be included in the minimum uniform  
 19 data set under subsection (a) and the standard for-  
 20 mat for such data.

21 (2) DESIGN.—Such specification shall—

22 (A) take into consideration the different  
 23 populations served (such as children and indi-  
 24 viduals with disabilities);

1           (B) be consistent where appropriate with  
 2 requirements applicable to Medicare+Choice  
 3 health plans under 1851(d)(4)(D) of the Social  
 4 Security Act;

5           (C) take into consideration such dif-  
 6 ferences in the delivery system among group  
 7 health plans and health insurance issuers as the  
 8 Secretary deems appropriate;

9           (D) be consistent with standards adopted  
 10 to carry out part C of title XI of the Social Se-  
 11 curity Act; and

12           (E) be consistent where feasible with exist-  
 13 ing health plan quality indicators and measures  
 14 used by employers and purchasers.

15       (3) MINIMUM DATA.—The data in such set  
 16 shall include, to the extent determined feasible by  
 17 the appropriate Secretary, at least—

18           (A) data on process measures of clinical  
 19 performance for health care services provided  
 20 by health care professionals and facilities;

21           (B) data on outcomes measures of morbid-  
 22 ity and mortality including to the extent fea-  
 23 sible and appropriate data for pediatric and  
 24 gender-specific measures; and

1 (C) data on data on satisfaction of such in-  
2 dividuals, including data on voluntary  
3 disenrollment and grievances.

4 The minimum data set under this paragraph shall  
5 be established by the appropriate Secretaries using  
6 a negotiated rulemaking process under subchapter  
7 III of chapter 5 of title 5, United States Code.

8 (c) DISSEMINATION OF INFORMATION.—

9 (1) IN GENERAL.—The Director shall publicly  
10 disseminate (through printed media and the Inter-  
11 net) information on the aggregate data submitted  
12 under this section.

13 (2) FORMATS.—The information shall be dis-  
14 seminated in a manner that provides for a compari-  
15 son of health care quality among different group  
16 health plans and health insurance issuers, with ap-  
17 propriate differentiation by delivery system. In dis-  
18 seminating the information, the Director may ref-  
19 erence an appropriate benchmark (or benchmarks)  
20 for performance with respect to specific quality indi-  
21 cators and measures (or groups of such measures).

22 (d) HEALTH CARE QUALITY RESEARCH AND INFOR-  
23 MATION.—The Secretary of Health and Human Services,  
24 acting through the Director, shall conduct and support re-  
25 search demonstration projects, evaluations, and the dis-

1 semination of information with respect to measurement,  
2 status, improvement, and presentation of quality indica-  
3 tors and measures and other health care quality informa-  
4 tion.

5 (e) NATIONAL REPORTS ON HEALTH CARE QUAL-  
6 ITY.—

7 (1) REPORT ON NATIONAL GOALS.—Not later  
8 than 18 months after the date of enactment of this  
9 Act, and every 2 years thereafter, the Secretary of  
10 Health and Human Services shall prepare and sub-  
11 mit to the appropriate committees of Congress and  
12 the President a report that—

13 (A) establishes national goals for the im-  
14 provement of the quality of health care; and

15 (B) contains recommendations for achiev-  
16 ing the national goals established under para-  
17 graph (1).

18 (2) REPORT ON HEALTH RELATED TOPICS.—  
19 Not later than 30 months after the date of enact-  
20 ment of this Act and every 2 years thereafter, such  
21 Secretary shall prepare and submit to Congress and  
22 the President a report that addresses at least 1 of  
23 the following (or a related matter):

1           (A) The availability, applicability, and ap-  
2           propriateness of information to consumers re-  
3           garding the quality of their health care.

4           (B) The state of information systems and  
5           data collecting capabilities for measuring and  
6           reporting on quality indicators.

7           (C) The impact of quality measurement on  
8           access to and the cost of medical care.

9           (D) Barriers to continuous quality im-  
10          provement in medical care.

11          (E) The state of health care quality meas-  
12          urement research and development.

13          (f) AUTHORIZATION OF APPROPRIATIONS.—There  
14          are authorized to be appropriated \$25,000,000 for each  
15          fiscal year (beginning with fiscal year 2000) to carry out  
16          this section. Any such amounts appropriated for a fiscal  
17          year shall remain available, without fiscal year limitation,  
18          until expended.

19          (g) QUALITY INDICATORS AND MEASURES DE-  
20          FINED.—For purposes of this section, the term “quality  
21          indicators and measures” means structural characteris-  
22          tics, patient-encounter data, and the subsequent health  
23          status change of a patient as a result of health care serv-  
24          ices provided by health care professionals and facilities.

1 **SEC. 113. CONFIDENTIALITY AND ACCURACY OF ENROLLEE**

2 **RECORDS.**

3 A group health plan or a health insurance issuer shall  
4 establish procedures with respect to medical records or  
5 other health information maintained regarding partici-  
6 pants, beneficiaries, and enrollees to safeguard the privacy  
7 of any individually identifiable information about them.

8 **SEC. 114. QUALITY ASSURANCE.**

9 (a) **REQUIREMENT.**—A group health plan, and a  
10 health insurance issuer that offers health insurance cov-  
11 erage, shall establish and maintain an ongoing, internal  
12 quality assurance and continuous quality improvement  
13 program that meets the requirements of subsection (b).

14 (b) **PROGRAM REQUIREMENTS.**—The requirements of  
15 this subsection for a quality improvement program of a  
16 plan or issuer are as follows:

17 (1) **ADMINISTRATION.**—The plan or issuer has  
18 an identifiable unit with responsibility for adminis-  
19 tration of the program.

20 (2) **WRITTEN PLAN.**—The plan or issuer has a  
21 written plan for the program that is updated annu-  
22 ally and that specifies at least the following:

23 (A) The activities to be conducted.

24 (B) The organizational structure.

25 (C) The duties of the medical director.

1 (D) Criteria and procedures for the assess-  
2 ment of quality.

3 (3) SYSTEMATIC REVIEW.—The program pro-  
4 vides for systematic review of the type of health  
5 services provided, consistency of services provided  
6 with good medical practice, and patient outcomes.

7 (4) QUALITY CRITERIA.—The program—

8 (A) uses criteria that are based on per-  
9 formance and patient outcomes where feasible  
10 and appropriate;

11 (B) includes criteria that are directed spe-  
12 cifically at meeting the needs of at-risk popu-  
13 lations and covered individuals with chronic  
14 conditions or severe illnesses, including gender-  
15 specific criteria and pediatric-specific criteria  
16 where available and appropriate;

17 (C) includes methods for informing covered  
18 individuals of the benefit of preventive care and  
19 what specific benefits with respect to preventive  
20 care are covered under the plan or coverage;  
21 and

22 (D) makes available to the public a de-  
23 scription of the criteria used under subpara-  
24 graph (A).

1           (5) SYSTEM FOR IDENTIFYING.—The program  
2       has procedures for identifying possible quality con-  
3       cerns by providers and enrollees and for remedial ac-  
4       tions to correct quality problems, including written  
5       procedures for responding to concerns and taking  
6       appropriate corrective action.

7           (6) DATA ANALYSIS.—The program provides,  
8       using data that include the data collected under sec-  
9       tion 112, for an analysis of the plan’s or issuer’s  
10      performance on quality measures.

11          (7) DRUG UTILIZATION REVIEW.—The program  
12      provides for a drug utilization review program  
13      which—

14           (A) encourages appropriate use of prescrip-  
15      tion drugs by participants, beneficiaries, and  
16      enrollees and providers, and

17           (B) takes appropriate action to reduce the  
18      incidence of improper drug use and adverse  
19      drug reactions and interactions.

20          (c) DEEMING.—For purposes of subsection (a), the  
21      requirements of—

22           (1) subsection (b) (other than paragraph (5))  
23      are deemed to be met with respect to a health insur-  
24      ance issuer that is a qualified health maintenance

1 organization (as defined in section 1310(c) of the  
2 Public Health Service Act); or

3 (2) subsection (b) are deemed to be met with  
4 respect to a health insurance issuer that is accred-  
5 ited by a national accreditation organization that the  
6 Secretary certifies as applying, as a condition of cer-  
7 tification, standards at least as stringent as those re-  
8 quired for a quality improvement program under  
9 subsection (b).

10 (d) VARIATION PERMITTED.—The Secretary may  
11 provide for variations in the application of the require-  
12 ments of this section to group health plans and health in-  
13 surance issuers based upon differences in the delivery sys-  
14 tem among such plans and issuers as the Secretary deems  
15 appropriate.

16 (e) CONSULTATION IN MEDICAL POLICIES.—A group  
17 health plan, and health insurance issuer that offers health  
18 insurance coverage, shall consult with participating physi-  
19 cians (if any) regarding the plan’s or issuer’s medical pol-  
20 icy, quality, and medical management procedures.

## 21 **Subtitle C—Patient Protection** 22 **Standards**

### 23 **SEC. 121. EMERGENCY SERVICES.**

24 (a) COVERAGE OF EMERGENCY SERVICES.—

1           (1) IN GENERAL.—If a group health plan, or  
2           health insurance coverage offered by a health insur-  
3           ance issuer, provides any benefits with respect to  
4           emergency services (as defined in paragraph (2)(B)),  
5           the plan or issuer shall cover emergency services fur-  
6           nished under the plan or coverage—

7                   (A) without the need for any prior author-  
8                   ization determination;

9                   (B) whether or not the health care pro-  
10                  vider furnishing such services is a participating  
11                  provider with respect to such services;

12                  (C) in a manner so that, if such services  
13                  are provided to a participant, beneficiary, or en-  
14                  rollee by a nonparticipating health care provider  
15                  the participant, beneficiary, or enrollee is not  
16                  liable for amounts that exceed the amounts of  
17                  liability that would be incurred if the services  
18                  were provided by a participating health care  
19                  provider; and

20                  (D) without regard to any other term or  
21                  condition of such plan or coverage (other than  
22                  exclusion or coordination of benefits, or an af-  
23                  filiation or waiting period, permitted under sec-  
24                  tion 2701 of the Public Health Service Act, sec-  
25                  tion 701 of the Employee Retirement Income

1 Security Act of 1974, or section 9801 of the  
 2 Internal Revenue Code of 1986, and other than  
 3 applicable cost-sharing).

4 (2) DEFINITIONS.—In this section:

5 (A) EMERGENCY MEDICAL CONDITION  
 6 BASED ON PRUDENT LAYPERSON STANDARD.—  
 7 The term “emergency medical condition” means  
 8 a medical condition manifesting itself by acute  
 9 symptoms of sufficient severity (including se-  
 10 vere pain) such that a prudent layperson, who  
 11 possesses an average knowledge of health and  
 12 medicine, could reasonably expect the absence  
 13 of immediate medical attention to result in a  
 14 condition described in clause (i), (ii), or (iii) of  
 15 section 1867(e)(1)(A) of the Social Security  
 16 Act.

17 (B) EMERGENCY SERVICES.—The term  
 18 “emergency services” means—

19 (i) a medical screening examination  
 20 (as required under section 1867 of the So-  
 21 cial Security Act) that is within the capa-  
 22 bility of the emergency department of a  
 23 hospital, including ancillary services rou-  
 24 tinely available to the emergency depart-  
 25 ment to evaluate an emergency medical

1 condition (as defined in subparagraph  
2 (A)), and

3 (ii) within the capabilities of the staff  
4 and facilities available at the hospital, such  
5 further medical examination and treatment  
6 as are required under section 1867 of such  
7 Act to stabilize the patient.

8 (b) REIMBURSEMENT FOR MAINTENANCE CARE AND  
9 POST-STABILIZATION CARE.—In the case of services  
10 (other than emergency services) for which benefits are  
11 available under a group health plan, or under health insur-  
12 ance coverage offered by a health insurance issuer, the  
13 plan or issuer shall provide for reimbursement with re-  
14 spect to such services provided to a participant, bene-  
15 ficiary, or enrollee other than through a participating  
16 health care provider in a manner consistent with sub-  
17 section (a)(1)(C) if the services are maintenance care or  
18 post-stabilization care covered under the guidelines estab-  
19 lished under section 1852(d)(2) of the Social Security Act  
20 (relating to promoting efficient and timely coordination of  
21 appropriate maintenance and post-stabilization care of an  
22 enrollee after an enrollee has been determined to be sta-  
23 ble), in accordance with regulations established to carry  
24 out such section.

1 **SEC. 122. ENROLLEE CHOICE OF HEALTH PROFESSIONALS**  
2 **AND PROVIDERS.**

3 (a) CHOICE OF PERSONAL HEALTH PROFES-  
4 SIONAL.—

5 (1) PRIMARY CARE.—A group health plan, and  
6 a health insurance issuer that offers health insur-  
7 ance coverage, shall permit each participant, bene-  
8 ficiary, and enrollee—

9 (A) to receive primary care from any par-  
10 ticipating primary care provider who is avail-  
11 able to accept such individual, and

12 (B) in the case of a participant, bene-  
13 ficiary, or enrollee who has a child who is also  
14 covered under the plan or coverage, to des-  
15 ignate a participating physician who specializes  
16 in pediatrics as the child's primary care pro-  
17 vider.

18 (2) SPECIALISTS.—

19 (A) IN GENERAL.—Subject to subpara-  
20 graph (B), a group health plan and a health in-  
21 surance issuer that offers health insurance cov-  
22 erage shall permit each participant, beneficiary,  
23 or enrollee to receive medically necessary or ap-  
24 propriate specialty care, pursuant to appro-  
25 priate referral procedures, from any qualified

1 participating health care provider who is avail-  
 2 able to accept such individual for such care.

3 (B) LIMITATION.—Subparagraph (A) shall  
 4 not apply to specialty care if the plan or issuer  
 5 clearly informs participants, beneficiaries, and  
 6 enrollees of the limitations on choice of partici-  
 7 pating providers with respect to such care.

8 (b) SPECIALIZED SERVICES.—

9 (1) OBSTETRICAL AND GYNECOLOGICAL  
 10 CARE.—

11 (A) IN GENERAL.—If a group health plan,  
 12 or a health insurance issuer in connection with  
 13 the provision of health insurance coverage, re-  
 14 quires or provides for a participant, beneficiary,  
 15 or enrollee to designate a participating primary  
 16 care provider, and an individual who is female  
 17 has not designated a participating physician  
 18 specializing in obstetrics and gynecology as a  
 19 primary care provider, the plan or issuer—

20 (i) may not require authorization or a  
 21 referral by the individual's primary care  
 22 provider or otherwise for coverage of rou-  
 23 tine gynecological care (such as preventive  
 24 women's health examinations) and preg-  
 25 nancy-related services provided by a par-

1            participating health care professional who spe-  
 2            cializes in obstetrics and gynecology to the  
 3            extent such care is otherwise covered, and

4            (ii) may treat the ordering of other  
 5            gynecological care by such a participating  
 6            physician as the authorization of the pri-  
 7            mary care provider with respect to such  
 8            care under the plan or coverage.

9            (B) CONSTRUCTION.—Nothing in subpara-  
 10          graph (A)(ii) shall waive any requirements of  
 11          coverage relating to medical necessity or appro-  
 12          priateness with respect to coverage of gynecolo-  
 13          gical care so ordered.

14          (2) SPECIALTY CARE.—

15                (A) SPECIALTY CARE FOR COVERED SERV-  
 16          ICES.—

17                        (i) IN GENERAL.—If—

18                                (I) an individual is a participant  
 19                                or beneficiary under a group health  
 20                                plan or an enrollee who is covered  
 21                                under health insurance coverage of-  
 22                                fered by a health insurance issuer,

23                                (II) the individual has a condi-  
 24                                tion or disease of sufficient serious-

1                   ness and complexity to require treat-  
2                   ment by a specialist, and

3                   (III) benefits for such treatment  
4                   are provided under the plan or cov-  
5                   erage,

6                   the plan or issuer shall make or provide for  
7                   a referral to a specialist who is available  
8                   and accessible to provide the treatment for  
9                   such condition or disease.

10                  (ii) SPECIALIST DEFINED.—For pur-  
11                  poses of this paragraph, the term “special-  
12                  ist” means, with respect to a condition, a  
13                  health care practitioner, facility, or center  
14                  (such as a center of excellence) that has  
15                  adequate expertise through appropriate  
16                  training and experience (including, in the  
17                  case of a child, appropriate pediatric exper-  
18                  tise) to provide high quality care in treat-  
19                  ing the condition.

20                  (iii) CARE UNDER REFERRAL.—A  
21                  group health plan or health insurance  
22                  issuer may require that the care provided  
23                  to an individual pursuant to such referral  
24                  under clause (i) be—

1 (I) pursuant to a treatment plan,  
 2 only if the treatment plan is developed  
 3 by the specialist and approved by the  
 4 plan or issuer, in consultation with  
 5 the designated primary care provider  
 6 or specialist and the individual (or the  
 7 individual's designee), and

8 (II) in accordance with applicable  
 9 quality assurance and utilization re-  
 10 view standards of the plan or issuer.

11 Nothing in this paragraph shall be con-  
 12 strued as preventing such a treatment plan  
 13 for an individual from requiring a special-  
 14 ist to provide the primary care provider  
 15 with regular updates on the specialty care  
 16 provided, as well as all necessary medical  
 17 information.

18 (iv) REFERRALS TO PARTICIPATING  
 19 PROVIDERS.—A group health plan or  
 20 health insurance issuer is not required  
 21 under clause (i) to provide for a referral to  
 22 a specialist that is not a participating pro-  
 23 vider, unless the plan or issuer does not  
 24 have an appropriate specialist that is avail-  
 25 able and accessible to treat the individual's

condition and that is a participating provider with respect to such treatment.

(v) TREATMENT OF NONPARTICIPATING PROVIDERS.—If a plan or issuer refers an individual to a nonparticipating specialist pursuant to clause (i), services provided pursuant to the approved treatment plan (if any) shall be provided at no additional cost to the individual beyond what the individual would otherwise pay for services received by such a specialist that is a participating provider.

(B) SPECIALISTS AS PRIMARY CARE PROVIDERS.—

(i) IN GENERAL.—A group health plan, or a health insurance issuer, in connection with the provision of health insurance coverage, shall have a procedure by which an individual who is a participant, beneficiary, or enrollee and who has an ongoing special condition (as defined in clause (iii)) may receive a referral to a specialist for such condition who shall be responsible for and capable of providing and coordinating the individual's primary and

specialty care. If such an individual's care would most appropriately be coordinated by such a specialist, such plan or issuer shall refer the individual to such specialist.

(ii) TREATMENT AS PRIMARY CARE PROVIDER.—Such specialist shall be permitted to treat the individual without a referral from the individual's primary care provider and may authorize such referrals, procedures, tests, and other medical services as the individual's primary care provider would otherwise be permitted to provide or authorize, subject to the terms of the treatment plan (referred to in subparagraph (A)(iii)(I)).

(iii) ONGOING SPECIAL CONDITION DEFINED.—In this subparagraph, the term “special condition” means a condition or disease that—

(I) is life-threatening, degenerative, or disabling, and

(II) requires specialized medical care over a prolonged period of time.

(iv) TERMS OF REFERRAL.—The provisions of clauses (iii) through (v) of sub-

1 paragraph (A) apply with respect to refer-  
2 rals under clause (i) of this subparagraph  
3 in the same manner as they apply to refer-  
4 rals under subparagraph (A)(i).

5 (C) STANDING REFERRALS.—

6 (i) IN GENERAL.—A group health  
7 plan, and a health insurance issuer in con-  
8 nection with the provision of health insur-  
9 ance coverage, shall have a procedure by  
10 which an individual who is a participant,  
11 beneficiary, or enrollee and who has a con-  
12 dition that requires ongoing care from a  
13 specialist may receive a standing referral  
14 to such specialist for treatment of such  
15 condition. If the plan or issuer, or if the  
16 primary care provider in consultation with  
17 the medical director of the plan or issuer  
18 and the specialist (if any), determines that  
19 such a standing referral is appropriate, the  
20 plan or issuer shall make such a referral to  
21 such a specialist.

22 (ii) TERMS OF REFERRAL.—The pro-  
23 visions of clauses (iii) through (v) of sub-  
24 paragraph (A) apply with respect to refer-  
25 rals under clause (i) of this subparagraph

1 in the same manner as they apply to refer-  
 2 rals under subparagraph (A)(i).

3 (c) CONTINUITY OF CARE.—

4 (1) IN GENERAL.—

5 (A) TERMINATION OF PROVIDER.—If a  
 6 contract between a group health plan, or a  
 7 health insurance issuer in connection with the  
 8 provision of health insurance coverage, and a  
 9 health care provider is terminated (as defined  
 10 in subparagraph (C)), or benefits or coverage  
 11 provided by a health care provider are termi-  
 12 nated because of a change in the terms of pro-  
 13 vider participation in a group health plan, and  
 14 an individual who is a participant, beneficiary,  
 15 or enrollee in the plan or coverage is under-  
 16 going a course of treatment from the provider  
 17 at the time of such termination, the plan or  
 18 issuer shall—

19 (i) notify the individual on a timely  
 20 basis of such termination, and

21 (ii) subject to paragraph (3), permit  
 22 the individual to continue or be covered  
 23 with respect to the course of treatment  
 24 with the provider during a transitional pe-  
 25 riod (provided under paragraph (2)) if the

1 plan or issuer is notified orally or in writ-  
2 ing of the facts and circumstances concern-  
3 ing the course of treatment.

4 (B) TREATMENT OF TERMINATION OF  
5 CONTRACT WITH HEALTH INSURANCE  
6 ISSUER.—If a contract for the provision of  
7 health insurance coverage between a group  
8 health plan and a health insurance issuer is ter-  
9 minated and, as a result of such termination,  
10 coverage of services of a health care provider is  
11 terminated with respect to an individual, the  
12 provisions of subparagraph (A) (and the suc-  
13 ceeding provisions of this section) shall apply  
14 under the group health plan in the same man-  
15 ner as if there had been a direct contract be-  
16 tween the group health plan and the provider  
17 that had been terminated, but only with respect  
18 to benefits that are covered under the group  
19 health plan after the contract termination.

20 (C) TERMINATION.—In this section, the  
21 term “terminated” includes, with respect to a  
22 contract, the expiration or nonrenewal of the  
23 contract, but does not include a termination of  
24 the contract by the plan or issuer for failure to  
25 meet applicable quality standards or for fraud.

1 (2) TRANSITIONAL PERIOD.—

2 (A) IN GENERAL.—Except as provided in  
3 subparagraphs (B) through (D), the transi-  
4 tional period under this subsection shall extend  
5 for at least 90 days from the date of the notice  
6 described in paragraph (1)(A)(i) of the provid-  
7 er's termination.

8 (B) INSTITUTIONAL CARE.—The transi-  
9 tional period under this subsection for institu-  
10 tional or inpatient care from a provider shall  
11 extend until the discharge or termination of the  
12 period of institutionalization and also shall in-  
13 clude institutional care provided within a rea-  
14 sonable time of the date of termination of the  
15 provider status.

16 (C) PREGNANCY.—If—

17 (i) a participant, beneficiary, or en-  
18 rollee has entered the second trimester of  
19 pregnancy at the time of a provider's ter-  
20 mination of participation, and

21 (ii) the provider was treating the  
22 pregnancy before date of the termination,  
23 the transitional period under this subsection  
24 with respect to provider's treatment of the  
25 pregnancy shall extend through the provision of

1 post-partum care directly related to the deliv-  
 2 ery.

3 (D) TERMINAL ILLNESS.—If—

4 (i) a participant, beneficiary, or en-  
 5 rollee was determined to be terminally ill  
 6 (as determined under section  
 7 1861(dd)(3)(A) of the Social Security Act)  
 8 at the time of a provider's termination of  
 9 participation, and

10 (ii) the provider was treating the ter-  
 11 minal illness before the date of termi-  
 12 nation,

13 the transitional period under this subsection  
 14 shall extend for the remainder of the individ-  
 15 ual's life for care directly related to the treat-  
 16 ment of the terminal illness, but in no case is  
 17 the transitional period required to extend for  
 18 longer than 180 days.

19 (3) PERMISSIBLE TERMS AND CONDITIONS.—A  
 20 group health plan or health insurance issuer may  
 21 condition coverage of continued treatment by a pro-  
 22 vider under paragraph (1)(A)(ii) upon the provider  
 23 agreeing to the following terms and conditions:

24 (A) The provider agrees to accept reim-  
 25 bursement from the plan or issuer and individ-

1 ual involved (with respect to cost-sharing) at  
2 the rates applicable prior to the start of the  
3 transitional period as payment in full (or, in the  
4 case described in paragraph (1)(B), at the rates  
5 applicable under the replacement plan or issuer  
6 after the date of the termination of the contract  
7 with the health insurance issuer) and not to im-  
8 pose cost-sharing with respect to the individual  
9 in an amount that would exceed the cost-shar-  
10 ing that could have been imposed if the contract  
11 referred to in paragraph (1)(A) had not been  
12 terminated.

13 (B) The provider agrees to adhere to the  
14 quality assurance standards of the plan or  
15 issuer responsible for payment under subpara-  
16 graph (A) and to provide to such plan or issuer  
17 necessary medical information related to the  
18 care provided.

19 (C) The provider agrees otherwise to ad-  
20 here to such plan's or issuer's policies and pro-  
21 cedures, including procedures regarding utiliza-  
22 tion review and referrals, and obtaining prior  
23 authorization and providing services pursuant  
24 to a treatment plan (if any) approved by the  
25 plan or issuer.

1           (4) CONSTRUCTION.—Nothing in this sub-  
 2           section shall be construed to require the coverage of  
 3           benefits which would not have been covered if the  
 4           provider involved remained a participating provider.

5           (d) PROTECTION AGAINST INVOLUNTARY  
 6           DISENROLLMENT BASED ON CERTAIN CONDITIONS.—

7           (1) IN GENERAL.—Subject to paragraph (2), a  
 8           group health plan and a health insurance issuer in  
 9           connection with the provision of health insurance  
 10          coverage may not disenroll an individual under the  
 11          plan or coverage because the individual's behavior is  
 12          considered disruptive, unruly, abusive, or uncoopera-  
 13          tive to the extent that the individual's continued en-  
 14          rollment under the coverage seriously impairs the  
 15          plan's or issuer's ability to furnish covered services  
 16          if the circumstances for the individual's behavior is  
 17          directly related to diminished mental capacity, severe  
 18          and persistent mental illness, or a serious childhood  
 19          mental and emotional disorder.

20          (2) EXCEPTION.—Paragraph (1) shall not  
 21          apply if the behavior engaged in directly threatens  
 22          bodily injury to any person.

23          (e) GENERAL ACCESS.—

24          (1) IN GENERAL.—Each group health plan, and  
 25          each health insurance issuer offering health insur-

1       ance coverage, that provides benefits, in whole or in  
 2       part, through participating health care providers  
 3       shall have (in relation to the coverage) a sufficient  
 4       number, distribution, and variety of qualified partici-  
 5       pating health care providers to ensure that all cov-  
 6       ered health care services, including specialty serv-  
 7       ices, will be available and accessible in a timely man-  
 8       ner to all participants, beneficiaries, and enrollees  
 9       under the plan or coverage.

10           (2) TREATMENT OF CERTAIN PROVIDERS.—The  
 11       qualified health care providers under paragraph (1)  
 12       may include Federally qualified health centers, rural  
 13       health clinics, migrant health centers, high-volume,  
 14       disproportionate share hospitals, and other essential  
 15       community providers located in the service area of  
 16       the plan or issuer and shall include such providers  
 17       if necessary to meet the standards established to  
 18       carry out such subsection.

19   **SEC. 123. ACCESS TO APPROVED SERVICES.**

20           (a) COVERAGE FOR INDIVIDUALS PARTICIPATING IN  
 21   APPROVED CLINICAL TRIALS.—

22           (1) COVERAGE.—

23           (A) IN GENERAL.—If a group health plan,  
 24       or health insurance issuer that is providing  
 25       health insurance coverage, provides coverage to

1 a qualified individual (as defined in paragraph  
2 (2)), the plan or issuer—

3 (i) may not deny the individual par-  
4 ticipation in the clinical trial referred to in  
5 paragraph (2)(B);

6 (ii) subject to paragraph (3), may not  
7 deny (or limit or impose additional condi-  
8 tions on) the coverage of routine patient  
9 costs for items and services furnished in  
10 connection with participation in the trial;  
11 and

12 (iii) may not discriminate against the  
13 individual on the basis of the enrollee's  
14 participation in such trial.

15 (B) EXCLUSION OF CERTAIN COSTS.—For  
16 purposes of subparagraph (A)(ii), routine pa-  
17 tient costs do not include the cost of the tests  
18 or measurements conducted primarily for the  
19 purpose of the clinical trial involved.

20 (C) USE OF IN-NETWORK PROVIDERS.—If  
21 one or more participating providers is partici-  
22 pating in a clinical trial, nothing in subpara-  
23 graph (A) shall be construed as preventing a  
24 plan or issuer from requiring that a qualified  
25 individual participate in the trial through such

1 a participating provider if the provider will ac-  
 2 cept the individual as a participant in the trial.

3 (2) QUALIFIED INDIVIDUAL DEFINED.—For  
 4 purposes of paragraph (1), the term “qualified indi-  
 5 vidual” means an individual who is a participant or  
 6 beneficiary in a group health plan, or who is an en-  
 7 rollee under health insurance coverage, and who  
 8 meets the following conditions:

9 (A)(i) The individual has a life-threatening  
 10 or serious illness for which no standard treat-  
 11 ment is effective.

12 (ii) The individual is eligible to participate  
 13 in an approved clinical trial according to the  
 14 trial protocol with respect to treatment of such  
 15 illness.

16 (iii) The individual’s participation in the  
 17 trial offers meaningful potential for significant  
 18 clinical benefit for the individual.

19 (B) Either—

20 (i) the referring physician is a partici-  
 21 pating health care professional and has  
 22 concluded that the individual’s participa-  
 23 tion in such trial would be appropriate  
 24 based upon the individual meeting the con-  
 25 ditions described in subparagraph (A); or

1 (ii) the participant, beneficiary, or en-  
2 rollee provides medical and scientific infor-  
3 mation establishing that the individual's  
4 participation in such trial would be appro-  
5 priate based upon the individual meeting  
6 the conditions described in subparagraph  
7 (A).

8 (3) PAYMENT.—

9 (A) IN GENERAL.—Under this subsection a  
10 group health plan or health insurance issuer  
11 shall provide for payment for routine patient  
12 costs described in paragraph (1)(A) but is not  
13 required to pay for costs of items and services  
14 that are reasonably expected (as determined by  
15 the Secretary) to be paid for by the sponsors of  
16 an approved clinical trial.

17 (B) PAYMENT RATE.—In the case of cov-  
18 ered items and services provided by—

19 (i) a participating provider, the pay-  
20 ment rate shall be at the agreed upon rate,  
21 or

22 (ii) a nonparticipating provider, the  
23 payment rate shall be at the rate the plan  
24 or issuer would normally pay for com-  
25 parable services under clause (i).

(4) APPROVED CLINICAL TRIAL DEFINED.—

(A) IN GENERAL.—In this subsection, the term “approved clinical trial” means a clinical research study or clinical investigation approved and funded (which may include funding through in-kind contributions) by one or more of the following:

(i) The National Institutes of Health.

(ii) A cooperative group or center of the National Institutes of Health.

(iii) Either of the following if the conditions described in subparagraph (B) are met:

(I) The Department of Veterans Affairs.

(II) The Department of Defense.

(B) CONDITIONS FOR DEPARTMENTS.—

The conditions described in this subparagraph, for a study or investigation conducted by a Department, are that the study or investigation has been reviewed and approved through a system of peer review that the Secretary determines—

(i) to be comparable to the system of peer review of studies and investigations

1           used by the National Institutes of Health,  
2           and

3                   (ii) assures unbiased review of the  
4           highest scientific standards by qualified in-  
5           dividuals who have no interest in the out-  
6           come of the review.

7           (5) CONSTRUCTION.—Nothing in this sub-  
8           section shall be construed to limit a plan’s or  
9           issuer’s coverage with respect to clinical trials.

10          (b) ACCESS TO PRESCRIPTION DRUGS.—

11               (1) IN GENERAL.—If a group health plan, or  
12           health insurance issuer that offers health insurance  
13           coverage, provides benefits with respect to prescrip-  
14           tion drugs but the coverage limits such benefits to  
15           drugs included in a formulary, the plan or issuer  
16           shall—

17                   (A) ensure participation of participating  
18           physicians and pharmacists in the development  
19           of the formulary; and

20                   (B) disclose to providers and, disclose upon  
21           request under section 111(c)(5) to participants,  
22           beneficiaries, and enrollees, the nature of the  
23           formulary restrictions; and

24                   (C) consistent with the standards for a uti-  
25           lization review program under section 102(a),

1           provide for exceptions from the formulary limi-  
2           tation when a non-formulary alternative is  
3           medically indicated.

4           (2) CONSTRUCTION.—Nothing in this sub-  
5           section shall be construed as requiring a group  
6           health plan (or health insurance issuer in connection  
7           with health insurance coverage) to provide any cov-  
8           erage of prescription drugs or as preventing such a  
9           plan or issuer from negotiating higher cost-sharing  
10          in the case a non-formulary alternative is provided  
11          under paragraph (1)(C).

12 **SEC. 124. NONDISCRIMINATION IN DELIVERY OF SERVICES.**

13          (a) APPLICATION TO DELIVERY OF SERVICES.—Sub-  
14          ject to subsection (b), a group health plan, and health in-  
15          surance issuer in relation to health insurance coverage,  
16          may not discriminate against a participant, beneficiary, or  
17          enrollee in the delivery of health care services consistent  
18          with the benefits covered under the plan or coverage or  
19          as required by law based on race, color, ethnicity, national  
20          origin, religion, sex, age, mental or physical disability, sex-  
21          ual orientation, genetic information, or source of payment.

22          (b) CONSTRUCTION.—Nothing in subsection (a) shall  
23          be construed as relating to the eligibility to be covered,  
24          or the offering (or guaranteeing the offer) of coverage,  
25          under a plan or health insurance coverage, the application

1 of any pre-existing condition exclusion consistent with ap-  
 2 plicable law, or premiums charged under such plan or cov-  
 3 erage. To the extent that health care providers are per-  
 4 mitted under State and Federal law to prioritize the ad-  
 5 mission or treatment of patients based on such patients'  
 6 individual religious affiliation, group health plans and  
 7 health insurance issuers may reflect those priorities in re-  
 8 ferring patients to such providers.

9 **SEC. 125. PROHIBITION OF INTERFERENCE WITH CERTAIN**  
 10 **MEDICAL COMMUNICATIONS.**

11 (a) IN GENERAL.—An organization on behalf of a  
 12 group health plan (as described in subsection (a)(2)) or  
 13 a health insurance issuer shall not penalize (financially or  
 14 otherwise) a health care professional for advocating on be-  
 15 half of his or her patient or for providing information or  
 16 referral for medical care (as defined in section 2791(a)(2)  
 17 of the Public Health Service Act) consistent with the  
 18 health care needs of the patient and with the code of ethi-  
 19 cal conduct, professional responsibility, conscience, medi-  
 20 cal knowledge, and license of the health care professional.

21 (b) CONSTRUCTION.—Nothing in subsection (a) shall  
 22 be construed as requiring a health insurance issuer or a  
 23 group health plan to pay for medical care not otherwise  
 24 paid for or covered by the plan provided by nonparticipat-  
 25 ing health care professionals, except in those instances and

1 to the extent that the issuer or plan would normally pay  
2 for such medical care.

3 (c) ASSISTANCE AND SUPPORT.—A group health plan  
4 or a health insurance issuer shall not prohibit or otherwise  
5 restrict a health care professional from providing letters  
6 of support to, or in any way assisting, enrollees who are  
7 appealing a denial, termination, or reduction of service in  
8 accordance with the procedures under subtitle A.

9 **SEC. 126. PROVIDER INCENTIVE PLANS.**

10 (a) PROHIBITION OF TRANSFER OF INDEMNIFICA-  
11 TION.—

12 (1) IN GENERAL.—No contract or agreement  
13 between a group health plan or health insurance  
14 issuer (or any agent acting on behalf of such a plan  
15 or issuer) and a health care provider shall contain  
16 any provision purporting to transfer to the health  
17 care provider by indemnification or otherwise any li-  
18 ability relating to activities, actions, or omissions of  
19 the plan, issuer, or agent (as opposed to the pro-  
20 vider).

21 (2) NULLIFICATION.—Any contract or agree-  
22 ment provision described in paragraph (1) shall be  
23 null and void.

24 (b) PROHIBITION OF IMPROPER PHYSICIAN INCEN-  
25 TIVE PLANS.—

1           (1) IN GENERAL.—A group health plan and a  
 2           health insurance issuer offering health insurance  
 3           coverage may not operate any physician incentive  
 4           plan (as defined in subparagraph (B) of section  
 5           1876(i)(8) of the Social Security Act) unless the re-  
 6           quirements described in subparagraph (A) of such  
 7           section are met with respect to such a plan.

8           (2) APPLICATION.—For purposes of carrying  
 9           out paragraph (1), any reference in section  
 10          1876(i)(8) of the Social Security Act to the Sec-  
 11          retary, an eligible organization, or an individual en-  
 12          rolled with the organization shall be treated as a ref-  
 13          erence to the applicable authority, a group health  
 14          plan or health insurance issuer, respectively, and a  
 15          participant, beneficiary, or enrollee with the plan or  
 16          organization, respectively.

17 **SEC. 127. PROVIDER PARTICIPATION.**

18          (a) IN GENERAL.—A group health plan and a health  
 19          insurance issuer that offers health insurance coverage  
 20          shall, if it provides benefits through participating health  
 21          care professionals, have a written process for the selection  
 22          of participating health care professionals under the plan  
 23          or coverage. Such process shall include—

24                (1) minimum professional requirements;

1           (2) providing notice of the rules regarding par-  
2       ticipation;

3           (3) providing written notice of participation de-  
4       cisions that are adverse to professionals; and

5           (4) providing a process within the plan or issuer  
6       for appealing such adverse decisions, including the  
7       presentation of information and views of the profes-  
8       sional regarding such decision.

9       (b) VERIFICATION OF BACKGROUND.—Such process  
10   shall include verification of a health care provider’s license  
11   and a history of suspension or revocation.

12       (c) RESTRICTION.—Such process shall not use a  
13   high-risk patient base or location of a provider in an area  
14   with residents with poorer health status as a basis for ex-  
15   cluding providers from participation.

16       (d) GENERAL NONDISCRIMINATION.—

17           (1) IN GENERAL.—Subject to paragraph (2),  
18       such process shall not discriminate with respect to  
19       selection of a health care professional to be a partici-  
20       pating health care provider, or with respect to the  
21       terms and conditions of such participation, based on  
22       the professional’s race, color, religion, sex, national  
23       origin, age, sexual orientation, or disability (consist-  
24       ent with the Americans with Disabilities Act of  
25       1990).

1           (2) RULES.—The appropriate Secretary may  
 2       establish such definitions, rules, and exceptions as  
 3       may be appropriate to carry out paragraph (1), tak-  
 4       ing into account comparable definitions, rules, and  
 5       exceptions in effect under employment-based non-  
 6       discrimination laws and regulations that relate to  
 7       each of the particular bases for discrimination de-  
 8       scribed in such paragraph.

9   **SEC. 128. REQUIRED COVERAGE FOR APPROPRIATE HOS-**  
 10                   **PITAL STAY FOR MASTECTOMIES AND LYMPH**  
 11                   **NODE DISSECTIONS FOR THE TREATMENT OF**  
 12                   **BREAST CANCER.**

13       (a) COVERAGE OF INPATIENT CARE FOR SURGICAL  
 14   TREATMENT OF BREAST CANCER.—

15           (1) IN GENERAL.—A group health plan, and a  
 16       health insurance issuer providing health insurance  
 17       coverage, that provides medical and surgical benefits  
 18       shall ensure that inpatient coverage with respect to  
 19       the surgical treatment of breast cancer (including a  
 20       mastectomy, lumpectomy, or lymph node dissection  
 21       for the treatment of breast cancer) is provided for  
 22       a period of time as is determined by the attending  
 23       physician, in his or her professional judgment con-  
 24       sistent with generally accepted principles of profes-

1 sional medical practice, in consultation with the pa-  
2 tient, to be medically necessary or appropriate.

3 (2) EXCEPTION.—Nothing in this section shall  
4 be construed as requiring the provision of inpatient  
5 coverage if the attending physician in consultation  
6 with the patient determine that a shorter period of  
7 hospital stay is medically necessary or appropriate.

8 (b) NO AUTHORIZATION REQUIRED.—

9 (1) IN GENERAL.—An attending physician shall  
10 not be required to obtain authorization from the  
11 plan or issuer for prescribing any length of stay in  
12 connection with a mastectomy, a lumpectomy, or a  
13 lymph node dissection for the treatment of breast  
14 cancer.

15 (2) PRENOTIFICATION.—Nothing in this section  
16 shall be construed as preventing a group health plan  
17 or health insurance issuer from requiring  
18 prenotification of an inpatient stay referred to in  
19 this section if such requirement is consistent with  
20 terms and conditions applicable to other inpatient  
21 benefits under the plan or health insurance coverage,  
22 except that the provision of such inpatient stay bene-  
23 fits shall not be contingent upon such notification.

1       (c) PROHIBITIONS.—A group health plan and a  
2 health insurance issuer offering health insurance coverage  
3 may not—

4           (1) deny to a patient eligibility, or continued  
5 eligibility, to enroll or to renew coverage under the  
6 terms of the plan or coverage, solely for the purpose  
7 of avoiding the requirements of this section;

8           (2) provide monetary payments or rebates to in-  
9 dividuals to encourage such individuals to accept less  
10 than the minimum protections available under this  
11 section;

12           (3) penalize or otherwise reduce or limit the re-  
13 imbursement of an attending provider because such  
14 provider provided care to an individual participant,  
15 beneficiary, or enrollee in accordance with this sec-  
16 tion;

17           (4) provide incentives (monetary or otherwise)  
18 to an attending provider to induce such provider to  
19 provide care to an individual participant, beneficiary,  
20 or enrollee in a manner inconsistent with this sec-  
21 tion; and

22           (5) subject to subsection (d)(2), restrict benefits  
23 for any portion of a period within a hospital length  
24 of stay required under subsection (a) in a manner

1       which is less favorable than the benefits provided for  
2       any preceding portion of such stay.

3       (d) RULES OF CONSTRUCTION.—

4           (1) IN GENERAL.—Nothing in this section shall  
5       be construed to require a patient who is a partici-  
6       pant, beneficiary, or enrollee—

7           (A) to undergo a mastectomy or lymph  
8       node dissection in a hospital; or

9           (B) to stay in the hospital for a fixed pe-  
10       riod of time following a mastectomy or lymph  
11       node dissection.

12       (2) COST SHARING.—Nothing in this section  
13       shall be construed as preventing a group health plan  
14       or issuer from imposing deductibles, coinsurance, or  
15       other cost-sharing in relation to benefits for hospital  
16       lengths of stay in connection with a mastectomy or  
17       lymph node dissection for the treatment of breast  
18       cancer under the plan or health insurance coverage,  
19       except that such coinsurance or other cost-sharing  
20       for any portion of a period within a hospital length  
21       of stay required under subsection (a) may not be  
22       greater than such coinsurance or cost-sharing for  
23       any preceding portion of such stay.

24       (3) LEVEL AND TYPE OF REIMBURSEMENTS.—

25       Nothing in this section shall be construed to prevent

1 a group health plan or a health insurance issuer  
2 from negotiating the level and type of reimburse-  
3 ment with a provider for care provided in accordance  
4 with this section.

5 **SEC. 129. PROMOTING GOOD MEDICAL PRACTICE.**

6 (a) PROHIBITING ARBITRARY LIMITATIONS OR CON-  
7 DITIONS FOR THE PROVISION OF SERVICES.—

8 (1) IN GENERAL.—A group health plan, and a  
9 health insurance issuer in connection with the provi-  
10 sion of health insurance coverage, may not arbitrar-  
11 ily interfere with or alter the decision of the treating  
12 physician regarding the manner or setting in which  
13 particular services are delivered if the services are  
14 medically necessary or appropriate for treatment or  
15 diagnosis to the extent that such treatment or diag-  
16 nosis is otherwise a covered benefit.

17 (2) CONSTRUCTION.—Paragraph (1) shall not  
18 be construed as prohibiting a plan or issuer from  
19 limiting the delivery of services to one or more  
20 health care providers within a network of such pro-  
21 viders.

22 (3) MANNER OR SETTING DEFINED.—In para-  
23 graph (1), the term “manner or setting” means the  
24 location of treatment, such as whether treatment is  
25 provided on an inpatient or outpatient basis, and the

1 duration of treatment, such as the number of days  
 2 in a hospital. Such term does not include the cov-  
 3 erage of a particular service or treatment.

4 (b) NO CHANGE IN COVERAGE.—Subsection (a) shall  
 5 not be construed as requiring coverage of particular serv-  
 6 ices the coverage of which is otherwise not covered under  
 7 the terms of the plan or coverage or from conducting utili-  
 8 zation review activities consistent with this subsection.

9 (c) MEDICAL NECESSITY OR APPROPRIATENESS DE-  
 10 FINED.—In subsection (a), the term “medically necessary  
 11 or appropriate” means, with respect to a service or benefit,  
 12 a service or benefit which is consistent with generally ac-  
 13 cepted principles of professional medical practice.

## 14 **Subtitle D—Enhanced Enforcement** 15 **Authority**

16 **SEC. 141. INVESTIGATIONS AND REPORTING AUTHORITY,**  
 17 **INJUNCTIVE RELIEF AUTHORITY, AND IN-**  
 18 **CREASED CIVIL MONEY PENALTY AUTHORITY**  
 19 **FOR SECRETARY OF HEALTH AND HUMAN**  
 20 **SERVICES FOR VIOLATIONS OF PATIENT PRO-**  
 21 **TECTION STANDARDS.**

22 (a) INVESTIGATIONS AND REPORTING AUTHORITY.—  
 23 (1) IN GENERAL.—For purposes of carrying out  
 24 sections 2722(b) and 2761(b) of the Public Health  
 25 Service Act with respect to enforcement of the provi-

1        sions of sections 2707 and 2753, respectively, of  
 2        such Act (as added by title II of this Act)—

3                (A) the Secretary of Health and Human  
 4        Services shall have the same authorities with  
 5        respect to compelling health insurance issuers  
 6        to produce information and to conducting inves-  
 7        tigations in cases of violations of such provi-  
 8        sions as the Secretary of Labor has under sec-  
 9        tion 504 of the Employee Retirement Income  
 10       Security Act of 1974 with respect to violations  
 11       of title I of such Act; and

12               (B) section 504(c) of the Employee Retire-  
 13       ment Income Security Act of 1974 shall apply  
 14       to investigations conducted under paragraph (1)  
 15       in the same manner as it applies to investiga-  
 16       tions conducted under title I of such Act.

17        (2) REPORTING AUTHORITY.—In exercising au-  
 18       thority under paragraph (1), the Secretary may  
 19       require—

20               (A) States that have indicated an intention  
 21       to assume authority under section 2722(a)(1)  
 22       or 2761(a) of the Public Health Service Act to  
 23       report to the Secretary on enforcement efforts  
 24       undertaken to assure compliance with the re-

1            requirements of sections 2707 and 2753, respec-  
 2            tively, of such Act; and

3            (B) health insurance issuers to submit re-  
 4            ports to assure compliance with such require-  
 5            ments.

6            (b) AUTHORITY FOR INJUNCTIVE RELIEF.—In addi-  
 7            tion to the authority referred to in subsection (a), the Sec-  
 8            retary of Health and Human Services has the same au-  
 9            thority with respect to enforcement of the provisions of  
 10          this title as the Secretary of Labor has under subsection  
 11          (a)(5) of section 502 of the Employee Retirement Income  
 12          Security Act of 1974 (as applied without regard to sub-  
 13          section (b) of that section) and the related provisions of  
 14          part 5 of subtitle B of title I of such Act with respect  
 15          to enforcement of such title I of such Act.

16          (c) INCREASE IN CIVIL MONEY PENALTIES.—

17            (1) IN GENERAL.—In the case of a civil money  
 18            penalty that may be imposed under section  
 19            2722(b)(2) or 2761(b) of the Public Health Service  
 20            Act with respect to a failure to meet the provisions  
 21            of sections 2707 and 2753, respectively, of such Act,  
 22            the maximum amount of penalty otherwise provided  
 23            under section 2722(b)(2)(C)(i) of such Act may, not-  
 24            withstanding the amounts specified in such section,

1 and subject to paragraph (2), be up to the greatest  
2 of the following:

3 (A) FAILURES INVOLVING UNREASONABLE  
4 DENIAL OR DELAY IN BENEFITS IMPACTING ON  
5 LIFE OR HEALTH.—In the case of a failure that  
6 results in an unreasonable denial or delay in  
7 benefits that has seriously jeopardized (or has  
8 substantial likelihood of seriously jeopardizing)  
9 the individual's life, health, or ability to regain  
10 or maintain maximum function or (in the case  
11 of a child under the age of 6) development, the  
12 greater of the following:—

13 (i) PATTERN OR PRACTICE FAIL-  
14 URE.—If the failure reflects a pattern or  
15 practice of wrongful conduct, \$250,000,  
16 plus the amount (if any) determined under  
17 paragraph (2).

18 (ii) OTHER FAILURES.—In the case of  
19 a failure that does not reflect a pattern or  
20 practice of wrongful conduct, \$50,000 for  
21 each individual involved, plus the amount  
22 (if any) determined under paragraph (2).

23 (B) OTHER FAILURES.—In the case of a  
24 failure not described in subparagraph (A), the  
25 greater of the following:

1 (i) PATTERN AND PRACTICE FAIL-  
 2 URES.—In the case of a failure that re-  
 3 flects a pattern or practice of wrongful  
 4 conduct \$50,000, plus the amount (if any)  
 5 determined under paragraph (2).

6 (ii) OTHER FAILURES.—In the case of  
 7 a failure that does not reflect a pattern or  
 8 practice of wrongful conduct, \$10,000 for  
 9 each individual involved, plus the amount  
 10 (if any) determined under paragraph (2).

11 (2) CONTINUING FAILURE WITHOUT CORREC-  
 12 TION.—In the case of a failure which is not cor-  
 13 rected within the first week beginning with the date  
 14 on which the failure is established, the maximum  
 15 amount of the penalty under paragraph (1) shall be  
 16 increased by \$10,000 for each full succeeding week  
 17 in which the failure is not so corrected.

18 (d) AUTHORIZATION OF APPROPRIATIONS.—In addi-  
 19 tion to any other amounts authorized to be appropriated,  
 20 there are authorized to be appropriated to the Secretary  
 21 of Health and Human Services such sums as may be nec-  
 22 essary to carry out this section.

1 **SEC. 142. AUTHORITY FOR SECRETARY OF LABOR TO IM-**  
2 **POSE CIVIL PENALTIES FOR VIOLATIONS OF**  
3 **PATIENT PROTECTION STANDARDS.**

4 (a) IN GENERAL.—Section 502(c) of the Employee  
5 Retirement Income Security Act of 1974 (29 U.S.C.  
6 1132(c)) is amended by redesignating paragraphs (6) and  
7 (7) as paragraphs (7) and (8), respectively, and by insert-  
8 ing after paragraph (5) the following new paragraph:

9 “(6)(A) The Secretary may assess a civil penalty  
10 against a person acting in the capacity of a fiduciary of  
11 a group health plan (as defined in 733(a)) so as to cause  
12 a violation of section 714.

13 “(B) Subject to subparagraph (C), the maximum  
14 amount which may be assessed under subparagraph (A)  
15 is the greatest of the following:

16 “(i) In the case of a failure that results in an  
17 unreasonable denial or delay in benefits that seri-  
18 ously jeopardized (or has substantial likelihood of se-  
19 riously jeopardizing) the individual’s life, health, or  
20 ability to regain or maintain maximum function or  
21 (in the case of a child under the age of 6) develop-  
22 ment, the greater of the following:

23 “(I) If the failure reflects a pattern or  
24 practice of wrongful conduct, \$250,000, plus  
25 the amount (if any) determined under subpara-  
26 graph (C).

1           “(II) In the case of a failure that does not  
 2           reflect a pattern or practice of wrongful con-  
 3           duct, \$50,000 for each individual involved, plus  
 4           the amount (if any) determined under subpara-  
 5           graph (C).

6           “(ii) In the case of a failure not described in  
 7           clause (i), the greater of the following:

8           “(I) In the case of a failure that reflects  
 9           a pattern or practice of wrongful conduct  
 10          \$50,000, plus the amount (if any) determined  
 11          under subparagraph (C).

12          “(II) In the case of a failure that does not  
 13          reflect a pattern or practice of wrongful con-  
 14          duct, \$10,000 for each individual involved, plus  
 15          the amount (if any) determined under subpara-  
 16          graph (C).

17          “(C) In the case of a failure which is not corrected  
 18          within the first week beginning with the date on which  
 19          the failure is established, the maximum amount of the  
 20          penalty under subparagraph (B) shall be increased by  
 21          \$10,000 for each full succeeding week in which the failure  
 22          is not so corrected.”.

23          (b) CONFORMING AMENDMENT.—Section 502(a)(6)  
 24          of such Act (29 U.S.C. 1132(a)(6)) is amended by striking

1 “paragraph (2), (4), (5), or (6)” and inserting “paragraph  
2 (2), (4), (5), (6), or (7)”.

3 (c) AUTHORIZATION OF APPROPRIATIONS.—In addi-  
4 tion to any other amounts authorized to be appropriated,  
5 there are authorized to be appropriated to the Secretary  
6 of Labor such sums as may be necessary to carry out the  
7 amendments made by this section.

## 8 **TITLE II—PATIENT PROTECTION** 9 **STANDARDS UNDER PUBLIC** 10 **HEALTH SERVICE ACT**

### 11 **SEC. 201. APPLICATION TO GROUP HEALTH PLANS AND** 12 **GROUP HEALTH INSURANCE COVERAGE.**

13 (a) IN GENERAL.—Subpart 2 of part A of title  
14 XXVII of the Public Health Service Act, as amended by  
15 the Omnibus Consolidated and Emergency Supplemental  
16 Appropriations Act, 1999 (Public Law 105-277), is  
17 amended by adding at the end the following new section:

#### 18 **“SEC. 2707. PATIENT PROTECTION STANDARDS.**

19 “(a) IN GENERAL.—Each group health plan shall  
20 comply with patient protection requirements under title I  
21 of the Promoting Responsible Managed Care Act of 1999,  
22 and each health insurance issuer shall comply with patient  
23 protection requirements under such title with respect to  
24 group health insurance coverage it offers, and such re-

1 requirements shall be deemed to be incorporated into this  
2 subsection.

3 “(b) NOTICE.—A group health plan shall comply with  
4 the notice requirement under section 711(d) of the Em-  
5 ployee Retirement Income Security Act of 1974 with re-  
6 spect to the requirements referred to in subsection (a) and  
7 a health insurance issuer shall comply with such notice  
8 requirement as if such section applied to such issuer and  
9 such issuer were a group health plan.”.

10 (b) CONFORMING AMENDMENT.—Section  
11 2721(b)(2)(A) of such Act (42 U.S.C. 300gg–21(b)(2)(A))  
12 is amended by inserting “(other than section 2707)” after  
13 “requirements of such subparts”.

14 (c) REFERENCE TO ENHANCED ENFORCEMENT AU-  
15 THORITY.—For provisions providing for enhanced author-  
16 ity to enforce the patient protection requirements of title  
17 I under the Public Health Service Act, see section 141.

18 **SEC. 202. APPLICATION TO INDIVIDUAL HEALTH INSUR-**  
19 **ANCE COVERAGE.**

20 Part B of title XXVII of the Public Health Service  
21 Act, as amended by the Omnibus Consolidated and Emer-  
22 gency Supplemental Appropriations Act, 1999 (Public  
23 Law 105-277), is amended by inserting after section 2753  
24 the following new section:

1 **“SEC. 2753. PATIENT PROTECTION STANDARDS.**

2       “(a) IN GENERAL.—Each health insurance issuer  
3 shall comply with patient protection requirements under  
4 title I of the Promoting Responsible Managed Care Act  
5 of 1999 with respect to individual health insurance cov-  
6 erage it offers, and such requirements shall be deemed to  
7 be incorporated into this subsection.

8       “(b) NOTICE.—A health insurance issuer under this  
9 part shall comply with the notice requirement under sec-  
10 tion 711(d) of the Employee Retirement Income Security  
11 Act of 1974 with respect to the requirements of such title  
12 as if such section applied to such issuer and such issuer  
13 were a group health plan.”.

14 **TITLE III—PATIENT PROTEC-**  
15 **TION STANDARDS UNDER**  
16 **THE EMPLOYEE RETIREMENT**  
17 **INCOME SECURITY ACT OF**  
18 **1974**

19 **SEC. 301. APPLICATION OF PATIENT PROTECTION STAND-**  
20 **ARDS TO GROUP HEALTH PLANS AND GROUP**  
21 **HEALTH INSURANCE COVERAGE UNDER THE**  
22 **EMPLOYEE RETIREMENT INCOME SECURITY**  
23 **ACT OF 1974.**

24       (a) IN GENERAL.—Subpart B of part 7 of subtitle  
25 B of title I of the Employee Retirement Income Security  
26 Act of 1974, as amended by the Omnibus Consolidated

1 and Emergency Supplemental Appropriations Act, 1999  
2 (Public Law 105–277), is amended by adding at the end  
3 the following new section:

4 **“SEC. 714. PATIENT PROTECTION STANDARDS.**

5       “(a) IN GENERAL.—Subject to subsection (b), a  
6 group health plan (and a health insurance issuer offering  
7 group health insurance coverage in connection with such  
8 a plan) shall comply with the requirements of title I of  
9 the Promoting Responsible Managed Care Act of 1999 (as  
10 in effect as of the date of the enactment of such Act),  
11 and such requirements shall be deemed to be incorporated  
12 into this subsection.

13       “(b) PLAN SATISFACTION OF CERTAIN REQUIRE-  
14 MENTS.—

15               “(1) SATISFACTION OF CERTAIN REQUIRE-  
16 MENTS THROUGH INSURANCE.—For purposes of  
17 subsection (a), insofar as a group health plan pro-  
18 vides benefits in the form of health insurance cov-  
19 erage through a health insurance issuer, the plan  
20 shall be treated as meeting the following require-  
21 ments of title I of the Promoting Responsible Man-  
22 aged Care Act of 1999 with respect to such benefits  
23 and not be considered as failing to meet such re-  
24 quirements because of a failure of the issuer to meet  
25 such requirements so long as the plan sponsor or its

1       representatives did not cause such failure by the  
2       issuer:

3               “(A) Section 121 (relating to access to  
4       emergency care).

5               “(B) Section 122 (relating to choice of  
6       providers).

7               “(C) Section 122(b) (relating to specialized  
8       services).

9               “(D) Section 122(c)(1)(A) (relating to con-  
10      tinuity in case of termination of provider con-  
11      tract) and section 122(c)(1)(B) (relating to  
12      continuity in case of termination of issuer con-  
13      tract), but only insofar as a replacement issuer  
14      assumes the obligation for continuity of care.

15              “(E) Section 123(a) (relating to coverage  
16      for individuals participating in approved clinical  
17      trials.)

18              “(F) Section 123(b) (relating to access to  
19      needed prescription drugs).

20              “(G) Section 122(e) (relating to adequacy  
21      of provider network).

22              “(H) Subtitle B (relating to consumer in-  
23      formation).

24              “(2) INFORMATION.—With respect to informa-  
25      tion required to be provided or made available under

1 section 111 of such Act, in the case of a group  
2 health plan that provides benefits in the form of  
3 health insurance coverage through a health insur-  
4 ance issuer, the Secretary shall determine the cir-  
5 cumstances under which the plan is not required to  
6 provide or make available the information (and is  
7 not liable for the issuer's failure to provide or make  
8 available the information), if the issuer is obligated  
9 to provide and make available (or provides and  
10 makes available) such information.

11 “(3) GRIEVANCE AND INTERNAL APPEALS.—  
12 With respect to the grievance system and internal  
13 appeals process required to be established under sec-  
14 tions 102 and 103 of such Act, in the case of a  
15 group health plan that provides benefits in the form  
16 of health insurance coverage through a health insur-  
17 ance issuer, the Secretary shall determine the cir-  
18 cumstances under which the plan is not required to  
19 provide for such system and process (and is not lia-  
20 ble for the issuer's failure to provide for such system  
21 and process), if the issuer is obligated to provide for  
22 (and provides for) such system and process.

23 “(4) EXTERNAL APPEALS.—Pursuant to rules  
24 of the Secretary, insofar as a group health plan en-  
25 ters into a contract with a qualified external appeal

entity for the conduct of external appeal activities in accordance with section 106 of such Act, the plan shall be treated as meeting the requirement of such section and is not liable for the entity's failure to meet any requirements under such section.

“(5) APPLICATION TO PROHIBITIONS.—Pursuant to rules of the Secretary, if a health insurance issuer offers health insurance coverage in connection with a group health plan and takes an action in violation of any of the following sections of such Act, the group health plan shall not be liable for such violation unless the plan caused such violation:

“(A) Section 124 (relating to non-discrimination in delivery of services).

“(B) Section 125 (relating to prohibition of interference with certain medical communications).

“(C) Section 126 (relating to provider incentive plans).

“(D) Section 102(b) (relating to providing medically necessary care).

“(6) CONSTRUCTION.—Nothing in this subsection shall be construed to affect or modify the responsibilities of the fiduciaries of a group health plan under part 4 of subtitle B.

1 (b) SATISFACTION OF ERISA CLAIMS PROCEDURE

2 REQUIREMENT.—Section 503 of such Act (29 U.S.C.

3 1133) is amended by inserting “(a)” after “SEC. 503.”

4 and by adding at the end the following new subsection:

5 “(b) In the case of a group health plan (as defined

6 in section 733) compliance with the requirements of sub-

7 title D (and section 113) of title I of the Promoting Re-

8 sponsible Managed Care Act of 1999 in the case of a

9 claims denial shall be deemed compliance with subsection

10 (a) with respect to such claims denial.”.

11 (c) CONFORMING AMENDMENTS.—(1) Section 732(a)

12 of such Act (29 U.S.C. 1185(a)) is amended by striking

13 “section 711” and inserting “sections 711 and 714”.

14 (2) The table of contents in section 1 of such Act

15 is amended by inserting after the item relating to section

16 713 the following new item:

“Sec. 714. Patient protection standards.”.

17 (3) Section 502(b)(3) of such Act (29 U.S.C.

18 1132(b)(3)) is amended by inserting “(other than section

19 144(b))” after “part 7”.

20 (d) REFERENCE TO ENHANCED ENFORCEMENT AU-

21 THORITY.—For provisions providing for enhanced author-

22 ity to enforce the patient protection requirements of title

23 I under the Employee Retirement Income Security Act of

24 1974, see section 142.

1 **SEC. 302. ENFORCEMENT FOR ECONOMIC LOSS CAUSED BY**  
2 **COVERAGE DETERMINATIONS.**

3 (a) IN GENERAL.—Section 502(c) of the Employee  
4 Retirement Income Security Act of 1974 (29 U.S.C.  
5 1132), as amended by section 142(a) of this Act, is  
6 amended by redesignating paragraphs (7) and (8) as para-  
7 graphs (8) and (9), respectively, and by inserting after  
8 paragraph (6) the following new paragraph:

9 “(7)(A) In any case in which—

10 “(i) a coverage determination (as defined in  
11 section 101(a)(2) of the Promoting Responsible  
12 Managed Care Act of 1999) under a group health  
13 plan (as defined in section 503(b)(8)) is not made  
14 on a timely basis or is made on such a basis but is  
15 not made in accordance with the terms of the plan,  
16 this title, or title I of such Act, and

17 “(ii) a participant or beneficiary suffers per-  
18 sonal injury (including loss of life, health, or the  
19 ability to regain or maintain maximum function or  
20 (in the case of a child under the age of 6) develop-  
21 ment) as a result of such coverage determination,

22 any person or persons who are responsible under the terms  
23 of the plan for the making of such coverage determination  
24 are liable to the aggrieved participant or beneficiary for  
25 the amount of the economic loss suffered by the partici-  
26 pant or beneficiary caused by such coverage determina-

1 tion. Any question of fact in any cause of action under  
2 this paragraph shall be based on the preponderance of the  
3 evidence after de novo review.

4 “(B) For purposes of subparagraph (A), the term  
5 ‘economic loss’ means any pecuniary loss (including the  
6 loss of earnings or other benefits related to employment,  
7 medical expense loss, replacement services loss, loss due  
8 to death, burial costs, and loss of business or employment  
9 opportunities) caused by the coverage determination. Such  
10 term does not include punitive damages or damages for  
11 pain and suffering, inconvenience, emotional distress,  
12 mental anguish, loss of consortium, injury to reputation,  
13 humiliation, and other nonpecuniary losses.

14 “(C) Nothing in this paragraph shall be construed as  
15 requiring exhaustion of administrative process in the case  
16 of severe bodily injury or death.

17 “(D) For purposes of subparagraph (A), the term  
18 ‘personal injury’ means a physical injury and includes an  
19 injury arising out of the treatment (or failure to treat)  
20 a mental illness or disease.”.

21 (b) EFFECTIVE DATE.—The amendments made by  
22 subsection (a) apply to coverage determinations made on  
23 or after the date of the enactment of this Act.

1 **TITLE IV—PATIENT PROTEC-**  
 2 **TION STANDARDS UNDER**  
 3 **THE INTERNAL REVENUE**  
 4 **CODE OF 1986**

5 **SEC. 401. AMENDMENTS TO THE INTERNAL REVENUE CODE**  
 6 **OF 1986**

7 Subchapter B of chapter 100 of the Internal Revenue  
 8 Code of 1986 (as amended by section 1531(a) of the Tax-  
 9 payer Relief Act of 1997) is amended—

10 (1) in the table of sections, by inserting after  
 11 the item relating to section 9812 the following new  
 12 item:

“Sec. 9813. Standard relating to patient protection standards.”;  
 and

13 (2) by inserting after section 9812 the follow-  
 14 ing:

15 **“SEC. 9813. STANDARD RELATING TO PATIENT PROTEC-**  
 16 **TION STANDARDS.**

17 “A group health plan shall comply with the require-  
 18 ments of title I of the Promoting Responsible Managed  
 19 Care Act of 1999 (as in effect as of the date of the enact-  
 20 ment of such Act), and such requirements shall be deemed  
 21 to be incorporated into this section.”.

1 **TITLE V—EFFECTIVE DATES; CO-**  
2 **ORDINATION IN IMPLEMEN-**  
3 **TATION**

4 **SEC. 501. EFFECTIVE DATES.**

5 (a) GROUP HEALTH COVERAGE.—

6 (1) IN GENERAL.—Subject to paragraph (2),  
7 the amendments made by sections 201(a), 301, and  
8 401 (and title I insofar as it relates to such sections)  
9 shall apply with respect to group health plans, and  
10 health insurance coverage offered in connection with  
11 group health plans, for plan years beginning on or  
12 after January 1, 2000 (in this section referred to as  
13 the “general effective date”) and also shall apply to  
14 portions of plan years occurring on and after such  
15 date.

16 (2) TREATMENT OF COLLECTIVE BARGAINING  
17 AGREEMENTS.—In the case of a group health plan  
18 maintained pursuant to 1 or more collective bargain-  
19 ing agreements between employee representatives  
20 and 1 or more employers ratified before the date of  
21 enactment of this Act, the amendments made by sec-  
22 tions 201(a), 301, and 401 (and title I insofar as it  
23 relates to such sections) shall not apply to plan  
24 years beginning before the later of—

1           (A) the date on which the last collective  
 2           bargaining agreement relating to the plan ter-  
 3           minates (determined without regard to any ex-  
 4           tension thereof agreed to after the date of en-  
 5           actment of this Act), or

6           (B) the general effective date.

7       For purposes of subparagraph (A), any plan amend-  
 8       ment made pursuant to a collective bargaining  
 9       agreement relating to the plan which amends the  
 10      plan solely to conform to any requirement added by  
 11      this Act shall not be treated as a termination of  
 12      such collective bargaining agreement.

13      (b) INDIVIDUAL HEALTH INSURANCE COVERAGE.—  
 14      The amendments made by section 202 shall apply with  
 15      respect to individual health insurance coverage offered,  
 16      sold, issued, renewed, in effect, or operated in the individ-  
 17      ual market on or after the general effective date.

18      **SEC. 502. COORDINATION IN IMPLEMENTATION.**

19      Section 104(1) of Health Insurance Portability and  
 20      Accountability Act of 1996 is amended by striking “this  
 21      subtitle (and the amendments made by this subtitle and  
 22      section 401)” and inserting “the provisions of part 7 of  
 23      subtitle B of title I of the Employee Retirement Income  
 24      Security Act of 1974, the provisions of parts A and C of  
 25      title XXVII of the Public Health Service Act, chapter 100

1 of the Internal Revenue Code of 1986, and title I of the  
2 Promoting Responsible Managed Care Act of 1999”.

